UNIVERSITI SAINS MALAYSIA

STUDY PROTOCOL:

EVALUATION OF SURGICAL CONDITION DURING LAPAROSCOPIC GYNAECOLOGICAL SURGERY IN PATIENT WITH MODERATE VS DEEP NEUROMUSCULAR BLOCK IN LOW PRESSURE PNEUMOPERITONEUM.

Researcher: DR UMAIRAH BINTI ESA (MMC 71514)

Co-researchers:

ASSOCIATE PROF DR RHENDRA HARDY B MOHAMAD ZAINI (MMC 32241, NSR 126684).

DR ZULFAKAR MAZLAN (MMC 46464, NSR: 132658)

DR SANIHAH CHE OMAR (MMC 44833, NSR: 132654)

DR AHMAD AKRAM OMAR (MMC 46516, NSR 130133)

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1-Introduction

Laparoscopic surgery has increasing popularity and slowly replacing conventional open surgery as it offers more benefit to patient and health care practitioner. The overall risk of complications during laparoscopic surgery is recognized to be lower than during laparotomy. Laparoscopic hysterectomy compare to open vaginal hysterectomy reduces postoperative pain, reduce post op analgesics requirement and shorter duration of hospital admission.[1]

However, the increase intra-abdominal pressure created during laparoscopic surgery can affect cardiovascular, pulmonary and renal physiology. Besides the risk of post-operative nausea and vomiting, it is also stated that the pneumoperitoneum created during laparoscopic surgery is an important factor in the cause of postoperative shoulder pain.[2] Traditionally pneumoperitoneum created at 15mmHg[3]. Insufflation of intraabdominal carbon dioxide may cause post-operative shoulder pain up to 70% in some study in gynaecologic laparoscopic surgery. [4]

Use a lower pressure pneumoperitoneum might decrease postoperative pain, decrease post-operative shoulder tip pain[5] and reduce the risk of laparoscopic related complication[6]. Many studies used lower insufflation of intraabdominal pressure as an intraoperative intervention to reduce the complication[7,8]. However, a lower intraabdominal pressure may worsen surgical space and increase the risk of conversion to open surgery.

Though many factors contribute to the quality of surgical space include non-modifiable such as obesity, previous abdominal surgery and modifiable factors such as anaesthesia related factor, patient position and intraabdominal pressure. Numerous studies also have been carried out showing that deep neuromuscular block improves surgical condition in different type of laparoscopic surgery includes robotic assisted laparoscopic surgery.[9,10,11]

Currently with the advancement of technology where neuromuscular monitoring is widely available and the selective reversal binding agent suggamadex where post-operative complication of inadequate reversal can be markedly reduced, several studies have been done to observe the benefit of low intraabdominal pressure with deep neuromuscular block to surgical space quality and intraoperative complication related to high pressure intraabdominal complication compare to usual moderate block.[9,10,12] However there is still few study objectively measure the possible effect of deep neuromuscular blocker on the surgical space and the ability of surgery to be completely done in low pressure pneumoperitoneum in laparoscopic gynaecological surgery.

We hypothesized that deep neuromuscular block compare to moderate neuromuscular block would reduce the rate of increasing intraabdominal pressure and con be completely done in lower pressure pneumoperitoneum and would improve laparoscopic space by measuring distance from the sacral promontory to the inserted trocar in patients undergoing laparoscopic gynaecological surgery.

2-Problem statement & Study rationale

- Laparoscopic surgery increases tremendously in the past decade in the era of enhance recovery after surgery (ERAS) , despite its many advantages increase intraabdominal pressure by intraabdominal carbon dioxide inflation produce respiratory, cardiac side effect.
- There are previous studies done that show deep neuromuscular blockage in laparoscopic surgery increase quality of surgical view in upper abdominal surgery, bariatric surgery, and extraperitoneal surgery like nephrectomy.
- However, there is still not enough study to prove superiority of deep neuromuscular block compare to moderate neuromuscular block.
- Therefore, further studies are still required to evaluate the benefit of deep neuromuscular block

3-Research question

1. Is maintaining laparoscopic gynaecological surgery with deep neuromuscular block, (PTC 0-1) reduce the rate of increasing intra-abdominal pressure to maintain optimal surgical conditions compare to patient receiving moderate neuromuscular block (PTC >2)
2. Is maintaining laparoscopic gynaecological surgery with deep neuromuscular block, (PTC 0-1) increase skin-sacral promontory distance compare to patient receiving moderate neuromuscular block (PTC >2)
3. Is maintaining laparoscopic gynaecological surgery with deep neuromuscular block, (PTC 0-1) provide better surgical space quality compare to patient receiving moderate neuromuscular block PTC >2
4. Does maintaining lower abdominal laparoscopic surgery with deep neuromuscular block, PTC 0-1 reduce post-operative pain and reduce post-operative shoulder tip pain compare to patient receiving moderate neuromuscular block PTC >2?

4-Objective

- **General:.** To evaluate the effect of deep neuromuscular blockade on surgical conditions during laparoscopic gynaecological under low-pressure pneumoperitoneum.

Specific:

1. To compare the rate of increasing intra-abdominal pressure (IAP) by the surgeon when they decide that the surgical conditions are inadequate for the operation in patient receiving deep neuromuscular block compare to moderate neuromuscular block in laparoscopic gynaecological surgery.
2. To compare quality of surgical space condition in patient receiving deep and moderate neuromuscular block in laparoscopic gynaecological surgery.
3. To compare skin to sacral promontory distance in patient in patient receiving moderate neuromuscular block and deep neuromuscular block in laparoscopic gynaecological surgery.
4. To compare the post-operative pain and shoulder tip pain in patient receiving deep neuromuscular block and moderate neuromuscular block in laparoscopic gynaecological surgery

5-Literature review

In the past decade, many studies have been done to evaluate the benefit of deep neuromuscular blocker in many types of laparoscopic surgery such as to the surgical space quality, duration of operation, post-operative pain and intraoperative complications.

Dubois et. Al in 2014 compare the surgical condition in deep neuromuscular block and shallow neuromuscular block in laparoscopic hysterectomy using 4-point surgical scale. It shows that better surgical rating scale in deep neuromuscular block. In 98 of the subjects 34 of subject show excellent surgical condition where only 21 patients in shallow group score excellent.

Madsen et. All had done multiple randomized controlled trial in 2015 and 2016 evaluating different outcome comparing deep neuromuscular block and moderate neuromuscular block in laparoscopic gynaecological surgery. In 2015, they investigated whether deep neuromuscular block compared with no neuromuscular block would increase surgical space by measuring distance from sacral promontory to the inserted trocar at pneumoperitoneum of 12 mmHg and 8mmHg[11]. At 12 mmHg pneumoperitoneum, deep neuromuscular block improved surgical space with a mean of 0.33 cm (95% confidence interval 0.07–0.59) ($P = 0.01$) which is statistically insignificant but at 8mmHg deep neuromuscular block significantly improved surgical space with a mean of 0.3 cm (95% confidence interval, 0.06–0.54) ($P = 0.005$). in this study, surgical condition during suturing fascia in deep

neuromuscular block is significantly better compare to moderate block(p=0.03) estimated by the gynaecologist on a 4-point subjective rating scale.

In the next randomized controlled study, Madsen study the incidence of post-operative shoulder tip pain and recovery after laparoscopic hysterectomy in low pressure pneumoperitoneum 8mmHg with deep neuromuscular block (post tetanic count 0 to 1) compared with standard-pressure pneumoperitoneum (12 mmHg) with moderate neuromuscular block. In this study the incidence of shoulder tip pain is significantly reduce in group lower pneumoperitoneum with deep neuromuscular block (p = 0.34) after 4 days but after 14 days, the p value is 0.74 which is insignificant.[14]

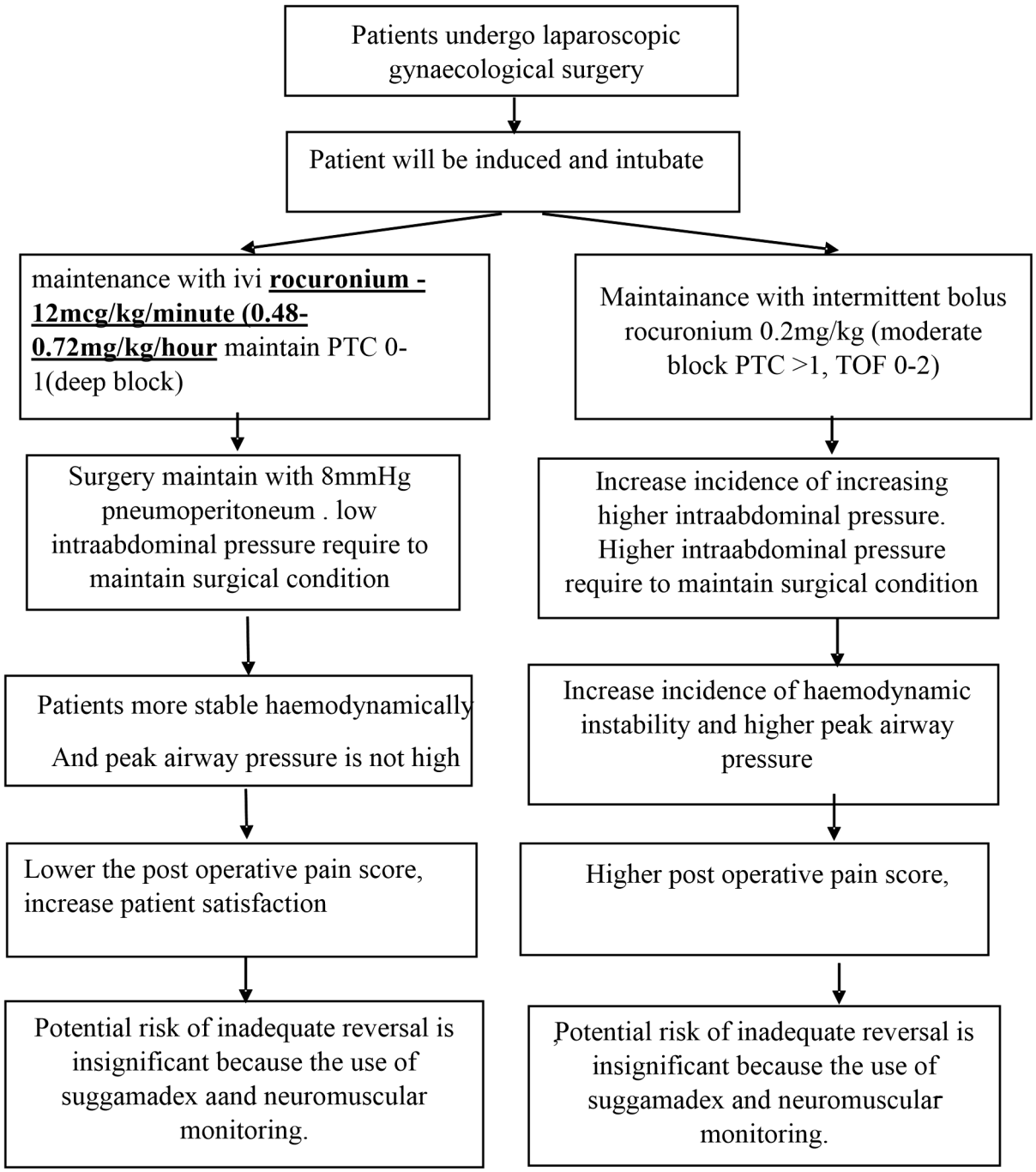
Meta-analysis in 2017 by M. H. Bruintjes include seven studies pooled in analyses surgical space condition. Overall surgical space condition improved in deep neuromuscular block by mean difference of 0.65 (95% CI: 0.47–0.83) on a scale of 1–5. Between study heterogeneity was 46%. In this meta-analysis also, 5 studies pooled to analyse post-operative pain in the post anaesthesia care unit (PACU) during the first hour after surgery, which show overall significant reduction of early postoperative pain in the group with deep neuromuscular blockage by mean difference 0.52 (95% CI: −0.71 to − 0.32) on an 11-point scale. [15]

Subsequent meta-analysis in 2018 by park et al analyse eleven RCTs involving 844 patients. The frequency of excellent or good operating conditions was higher with deep block compared with a moderate block (odds ratio 2.83, 95% confidence interval 1.34 to 5.99, P = 0.007, I2 = 59%). However further studies are required to address the heterogeneity.[16]

Recent meta-analysis in 2020 includes eight study in analysis of the surgical space conditions which provides evidence that low intraabdominal pressure+ deep neuromuscular block does improve surgical space conditions compared with low intraabdominal pressure + moderate neuromuscular block however there is no difference in post-operative pain and duration of surgery. [17] However different intraabdominal pressure uses and degree of neuromuscular blocker use is different which make the study cannot have a solid conclusion which protocol is more preferable. All meta analysis conclude that we still need further randomized controlled studies are warranted to address the heterogeneity and power shortage demonstrated by the meta-analysis.

Article code [no.]	Laparoscopic procedure	NMB level experimental group	NMB level control group	Number of patients	Surgical rating scale	Other outcome measure
Dubois [13] 2014	Hyst	Deep	Shallow	100	1–4	Duration
Martini 2014[18]	Prost/Nephr	Deep	Moderate	24	1–5	Duration, pain, comp
Staehr-Rye [19] 2014	Chol	Deep	Moderate	48	1–4	Dur, pain, Intraabdominal pressure
Yoo [20] 2015	Prost	Deep	Moderate	66	1–5	Duration , pain, intraabdominal pressure comp
Madsen [9] 2015	Gyn	Deep	No NMB	14	1–4	Intraabdominal pressure
Blobner [21] 2015	Chol	Deep	No NMB	50	0–100%	Duration, pain,
Barrio [22] 2016	Chol/Gyn	Deep	Moderate	41	NA	IAP, comp
Kim [9] 2016	Colorectal	Deep	Moderate	61	1–5	Dur, pain, LOS, IAP, comp
Koo [10] 2016	Chol	Deep	Moderate	64	1–4	Dur, pain, IAP, comp
Madsen [14] 2016	Hyst	Deep	Moderate	99	NA	Dur, pain, LOS, IAP, comp
Torensma [23] 2016	RYGB	Deep	Moderate	100	1–5	Duration, pain
Ozdemir [12] 2017	Donor nephrectomy	Deep	Moderate	34	1-5	Pain, abdominal pressure

6-Conceptual framework



7-Research design

- Study design : Single Centre, double blinded randomized controlled trial.

  In Hospital Universiti Sains Malaysia, we will randomize patient that fulfill inclusion criteria in a double-blind, randomize control trial comparing the rate of increasing intraabdominal pressure in low pressure pneumoperotoneum in laparoscopic gynaecological study.

- Sampling method : Simple random sampling

  Sample will be randomize either will be in moderate group or deep group by simple Surgeon and participant will be blinded to the study either in moderate or deep groups.

- Study period : October 2020 – June 2022 (18 months)
- Sampling time frame : October 2020 – October 2021(12 months)
- Study location : Single center-Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan

Study area

- Study location: single center-Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan

Study population

- Reference population: Adult patient schedule to undergo laparoscopic gynaecological surgery (laparoscopic hysterectomy and laparoscopic ovarian cystectomy in Hospital Universiti Sains Malaysia , Kubang Kerian, Kelantan
- Target population: Adult patient more than 18 years old schedule to undergo laparoscopic gynaecological surgery (laparoscopic hysterectomy and laparoscopic ovarian cystectomy in Hospital Universiti Sains Malaysia , Kubang Kerian, Kelantan
- Sampling frame: Adult patient more than 18 years old, ASA I and ASAII schedule to undergo laparoscopic gynaecological surgery (laparoscopic hysterectomy and laparoscopic ovarian cystectomy in Hospital Universiti Sains Malaysia , Kubang Kerian, Kelantan

8-Subject criteria

Inclusion criteria:

1. Age more than 18 years old
2. ASA I or II
3. schedule to undergo laparoscopic gynaecological surgery (laparoscopic hysterectomy and laparoscopic ovarian cystectomy in Hospital Universiti Sains Malaysia , Kubang Kerian, Kelantan

Exclusion criteria:

1. Allergy to study drugs (rocuronium, suggamadex)
2. Serious cardiac and respiratory disease (reactive airway disease, upper respiratory tract infection)
3. Neurological or neuromuscular disease (epilepsy, family history and history of malignant hyperthermia etc.)
4. Pregnancy
5. Morbid obesity BMI>35

Withdrawal criteria:

1. Conversion to open surgery

9- Sample size estimation

Specific objective	Statisticsal test	Sample size determination
1. Rate of increasing intraabdominal pressure	Chi-squared Test /dichotomous	-Type 1 error : 0.05 -Power 0.8 -Po (control subject): 0.6 base on previous study by Dubois et al.[13] -P1 (study subject) : 0.9 base on previous study dubois et. all -We are planning a study of independent cases and controls with 1 control(s) per case. -We will need to study 32 experimental subjects and 32 control subjects to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use an uncorrected chi-squared statistic to evaluate this null hypothesis. -With addition of 10% drop out, we need 70 sample to evaluate null hypothesis. -Software: power sample size calculation size app.
2. Surgical space quality	t.test	-Type I error = 0.05 -Power = 0.8 -True difference of surgical space quality between group Moderate (control) and deep group is 0.5 base on previous study[18] -Standard deviation of surgical space quality is 0.4 on a prior study[18] -Ratio of control to experimental patients = 1:1 -If the true difference in the experimental and control means is 0.5, we will need to study 11 experimental subjects and 11 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. -Include 10% drop out we need 24 subjects to reject null hypothesis -Software: PS – Power and Sample Size Calculation
3. Sacral promontory distance	T test	-Type I error = 0.05 -Power = 0.8

		-True difference of sacral promontory distance between group Moderate (control) and deep group is 0.38 base on previous study.[22] -Standard deviation of surgical space quality is 0.5 base on a prior study[22] -Ratio of control to experimental patients = 1:1 -In a previous study the response within each subject group was normally distributed with standard deviation 0.5. If the true difference in the experimental and control means is 0.38, we will need to study 28 experimental subjects and 28 control subjects to be able to reject the null hypothesis [22] - Include 10% droup out . we need 62 sample to reject null hypothesis. -Software: PS – Power and Sample Size Calculation
4, post-operative pain	T test	-Type I error = 0.05 -Power = 0.8 -True difference of pain score between group Moderate (control) and deep group is 1 base on previous study.[23] -Standard deviation of surgical space quality is 1.4 on a prior study[23] -Ratio of control to experimental patients = 1:1 - In a previous study the response within each subject group was normally distributed with standard deviation 1.4. If the true difference in the experimental and control means is 1, we will need to study 32 experimental subjects and 32 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. -Include 10% drop out. we need 70 sample to reject null hypothesis. -Software: PS – Power and Sample Size Calculation

Objective 1 require highest sample to reject null hypothesis. To reject all the specific objective, the study needs 35 sample in moderate group and 35 sample in deep group to reject all the null hypothesis. Total 70 samples are required.

10-Sampling method and subject recruitment

- Approval from Ethics Committee of University Sains Malaysia (USM) health campus will be obtained prior to the recruitment of the patients.
- Patient listed for elective laparoscopic gynaecological surgery, will be receive 1 day prior to operation day.
- Potential adult patients will be selected according to inclusion and exclusion criteria one day before operation done by principal investigator.
- Detailed explanation regarding study procedures will be explained and written inform consents will be obtained from patients by principal investigator one day before the operation.
- The fasting time for all patients will be at least 6 hours prior to surgery
- All consented patients will be randomly assigned into two group:

Group 1 (Induction with rocuronium 0.6mg/kg + maintenance with ivi rocuronium rocuronium 8-12mcg/kg/minute (0.48-0.72 mg/kg/hour maintain PTC 0-1(deep block). (Study Group)

Group 2 (Induction with rocuronium 0.6mg/kg + maintenance with intermittent rocuronium 0.2mg/kg bolus. maintain PTC >1, TOF 0-2). Moderate block. (Control Group)

- In operation room, baseline measurement of non-invasive blood pressure, mean arterial pressure, heart rate, pulse oximeter, electrocardiogram and oxygen saturation will be monitored at time T_0
- Prior to induction of anaesthesia, patients should have intravenous cannula inserted and either 0.9% sodium chloride or Ringer's lactate solution will commence.
- General anaesthesia will commence to both group with bolus intravenous fentanyl 100mcg, intravenous propofol 2mg/kg, intravenous rocuronium 0.6mg/kg as induction agent. Then intubate with PVC endotracheal tube.
- Neuromuscular monitoring at ulnar nerve will be attached to both groups using TOF watch, intubation at TOF 0
- Anaesthesia is maintained with inhalational anaesthetic agent at minimum alveolar concentration (MAC 1.0)
- Surgical team is blind to the medication. Unblind investigator is responsible for drug administration and neuromuscular monitoring
- Group 1 (Induction with rocuronium 0.6mg/kg + maintenance with intravenous infusion rocuronium ivi rocuronium 8-12mcg/kg/minute (0.48-0.72 mg/kg/hour . maintain PTC 0-1)

- Group 2 Induction with rocuronium 0.6mg/kg + maintenance with intermittent rocuronium bolus. maintain PTC >1, TOF 0-2)
- Pneumoperitoneum is created initial at 8mmHg
- Intravenous paracetamol 1g given after induction, and intravenous morphine 0.05mg/kg given
- After the insertion of trocha, intraabdominal pressure is set at 8mmHg. Skin sacral promontory distance is measured with the laparoscopic grasper through the trocha which inserted infraumbilically in 25 degree Trendelenburg position . A sterile ruler will be use to measure the distance from surgeon's mark to the end of grasper in centimetres.
- After the measurement , surgical procedure will continue as usual with intraabdominal pressure 8mmHg.
- There surgeon are allowed to to change IAP to 12mmhg if they decide that visual field is inadequate for the operation.
- At the end of surgery, infusion drug will discontinue, and neuromuscular drug will be reverse with Suggamadex base on TOF count for both group.
- At the end of operation, surgeon will rated the surgical condition at 4 point scale (1= excellent, 2= good, 3=acceptable, 4= poor)
- Intravenous dexamethasone 4mg will be given after induction, and intravenous ondansetron will be given 30 minute after the end of surgery for anti emetic.
- The entire laparoscopic surgery and intra-abdominal pressure levels will be recorded to enable any subsequent analysis if necessary.
- Post operatively at Post anaesthesia care unit, post op pain and shoulder tip pain will be evaluated at 30 minute and 24 hour Post operatively. Fentanyl is injected intravenously as needed in post anaesthesia care unit and dose will be recorded)
- Pain will be measured using an 11-point numerical rating scale (NRS), ranging from 0 (no pain) to 10 (most pain imaginable).
- Postoperatively patient will be monitor at recovery bay operation theatre for at least 30 minutes before discharge as standard post-operative monitoring before discharge to ward. Patient will be monitor with continuous vital sign monitoring similar to standard post-operative procedure.
- The intubation procedure, anaethesia conduct and extubation procedure stated is similar using standard procedure as normal general anaesthesia is deliver to patient. **11-**

Operational definition

Moderate and deep neuromuscular block

Neuromuscular monitoring will be placed on patient ulnar nerve.

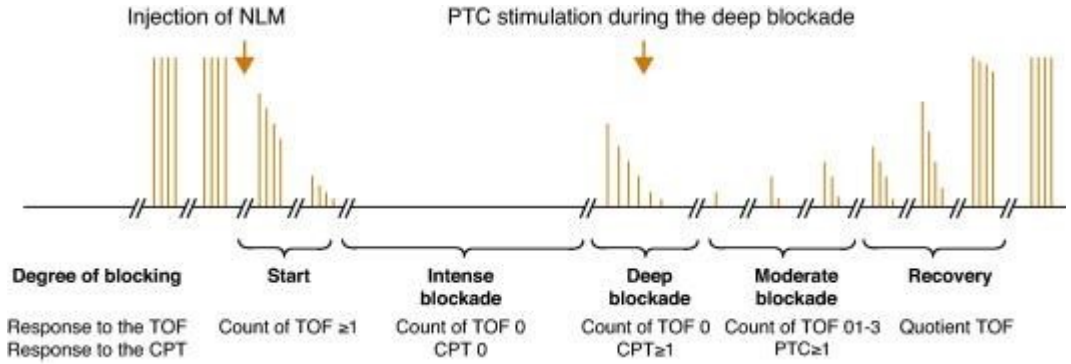


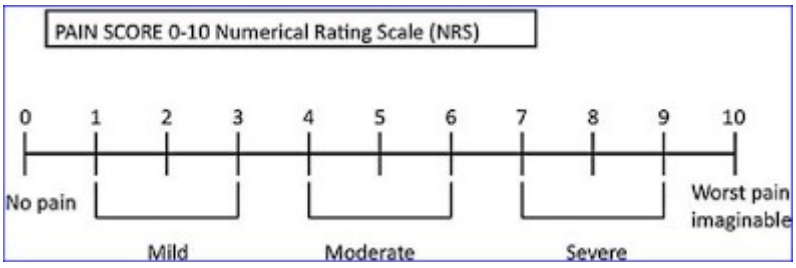
Table from: Joaquín Fabregat López, César Augusto Candia Arana, Caridad Greta Castillo Monzón, Neuromuscular monitoring and its importance in the use of neuromuscular blockers,Colombian Journal of Anesthesiology, Volume 40, Issue 4, November – December 2012, Pages 293-303.

Moderate block define as train of four (TOF) 0-2and Post tetanic count (PTC) > 1 whereas Deep block define as TOF 0 and PTC 0-1)

Low pressure pneumoperitoneum is defined as intraabdominal pressure 8mmHg. Rate of increasing intraabdominal pressure define as rate of conversion of intraabdominal pressure from 8mmHg to 12mmhg

Quality of surgical space condition define as 1: excellent , 2: good but not optimum, 3: poor but acceptable, 4: unacceptable [13]

Pain score describe as ;



12- Data collection method, research tools and data analysis

A- Data collection

Data collection shall be done by the primary investigator using assessment form. The details to be filled in the form include patient general demographic data (age, gender, weight), surgical procedure, airway details (number of intubation attempts, intubation condition scoring, time of surgery, skin sacral promontory distance, surgical condition score, pain at 30 minute and 24 hour and fentanyl requirement. Haemodynamic response also recorded

B- Research tool and Data analysis

Data will be entered and analysed using SPSS version *22*. Descriptive statistics will be used to summarise the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data will be presented as frequency (percentage). Paired sample t test will be use compare continous variable where chi square test will be used to test proportion. our first objective will be analyze using chi square test. Where other objective will be test using student t test.

C- **Expected result(s)**

Patient demographic data

	Moderate block (n=35)	Deep block (n=35)	P
Age (y)			
Weight (kg)			
Height(cm)			
BMI (Kg/m)			
ASA 1/2			
Previous abdominal surgery (yes/no)			

OBJECTIVE1: RATE OF INCREASING INTRAABDOMINAL PRESSURE

	Moderate (n=35)	Deep (n=35)	P
Increase of Intraabdominal pressure (%)			
Operation time (min)			
Anaesthesia time(min)			

OBJECTIVE 2: SURGICAL CONDITION SCORE

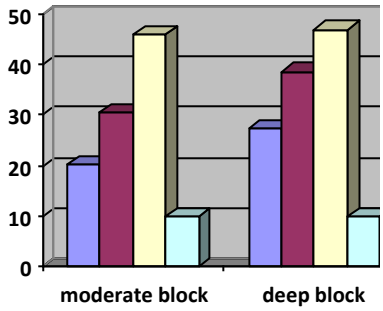


Figure 1: The distribution of 4 point surgical condition score

OBJECTIVE 3 : SKIN-SACRAL PROMONTORY DISTANCE

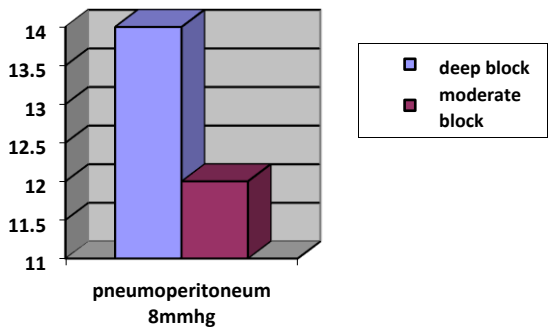


Figure 2 comparison of Mean skin sacral promotary distanceat moderate and deep block

OBJECTIVE 4 : POST OPERATIVE VARIABLE . VALUE AREA MEANS, MEDIAN OR NUMBER

	Moderate block (n=35)	Deep block (n=35)	P
Post operative pain (30minute)			
Post operative shoulder tip pain (30minute)			
Post operative pain (24H)			
Post operative shoulder tip pain (24 hour)			
Fentanyl requirement at recovery (µg)			

D- DATA COLLECTION FORM

DATA COLLECTION FORM : Evaluation of surgical condition during laparoscopic gynaecological surgery in patient with moderate vs deep neuromuscular block in lower pressure pneumoperitoneum.

Study Id:

Age: years month Gender: M/ F
Ethnicity: M / C / I / Others

Weight:

Height:

ASA : I/ II (If ASA II, state the disease/s:
Evaluation of pain score at PACU
Diagnosis:

Surgical procedure:

Previous abdominal sugery: (yes/ no)

Anaesthetist's year of experience:

Surgeon years of experience: <5

years 5-10 years > 10 years

Surgery: start : ends:

Anaesthesia start: ends:

Group:

1.Skin sacral promontory distance- ____ (cm)

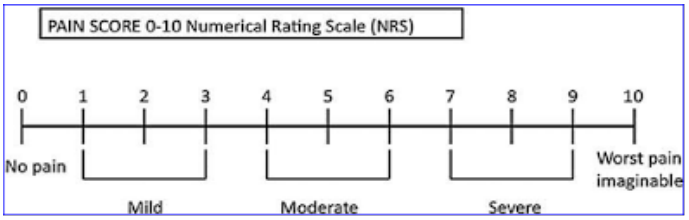
2. Surgery completed with intraabdominal pressure 8mmHg (Yes/ No)

If no Time increasing Intraabdominal Pressure ___H

3.Highest intraabdominal pressure use___ (mmhg)

3. surgical condition scale

	Surgical condition scale (tick 1 only)
1= excellent	
2=good but not optimal	
3=poor but acceptable	
4=unacceptable	



Total fentanyl requirement in recovery =___mcg

		Pain score	Shoulder tip pain score	MAP	HR
Arrived at PACU	T_0				
30 minute	T_3				

Evaluation of pain score in Ward

	pain score	Shoulder tip pain score	MAP	HR
24 Hour				

13-STUDY FLOW CHART

70 patients will be enrolled in the study:

35 group 1 (deep block PTC 0-1)

35 in group 2 (moderate block PTC >1, TOF 0-2)

Induction anesthesia:

- both group with intravenous fentanyl 100mcg,
- intravenous propofol 2mg/kg,
- intravenous rocuronium 0.6mg/kg.

Maintenance of anaesthesia:

- Anaesthesia is maintained with inhalational anaesthetic agent at minimum alveolar concentration (MAC 1.0)
- Group 1 -maintenance with ivi rocuronium **ivi rocuronium 8-12mcg/kg/minute (0.48-0.72 mg/kg/hour.** maintain PTC 0-1)
- Group 2 -maintenance with intermittent rocuronium bolus o.2 mg/kg. maintain PTC >1, TOF 0-2)

Analgesia:IV PCM1g , IV morphine 0.05mg/kg

Anti emetic: IV dexamethasone after induction, in ondansetron 4mg 30 minute before operation finish

Intra-operatively

- After the insertion of trocha, intraabdominal pressure is set at 8mmHg. Skin sacral promontory distance is measured with the laparoscopic grasper through the trocha which inserted infraumbilically in 25 degree Trendelenburg position . A sterile ruler will be use to measure the distance from surgeon's mark to the end of grasper in centimetres.
- After the measurement , surgical procedure will continue as usual with intraabdominal pressure 8mmHg.
- There surgeon are allowed to to change IAP to 12mmhg if they decide that visual field is inadequate for the operation.

- At the end of surgery, infusion drug will discontinue, and neuromuscular drug will be reverse with Suggamadex base on TOF count for both group.
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- The entire laparoscopic surgery and intra-abdominal pressure levels will be recorded to enable any subsequent analysis if necessary.
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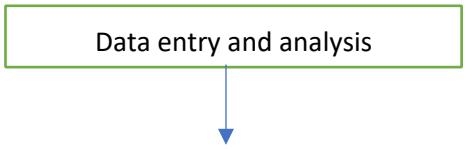
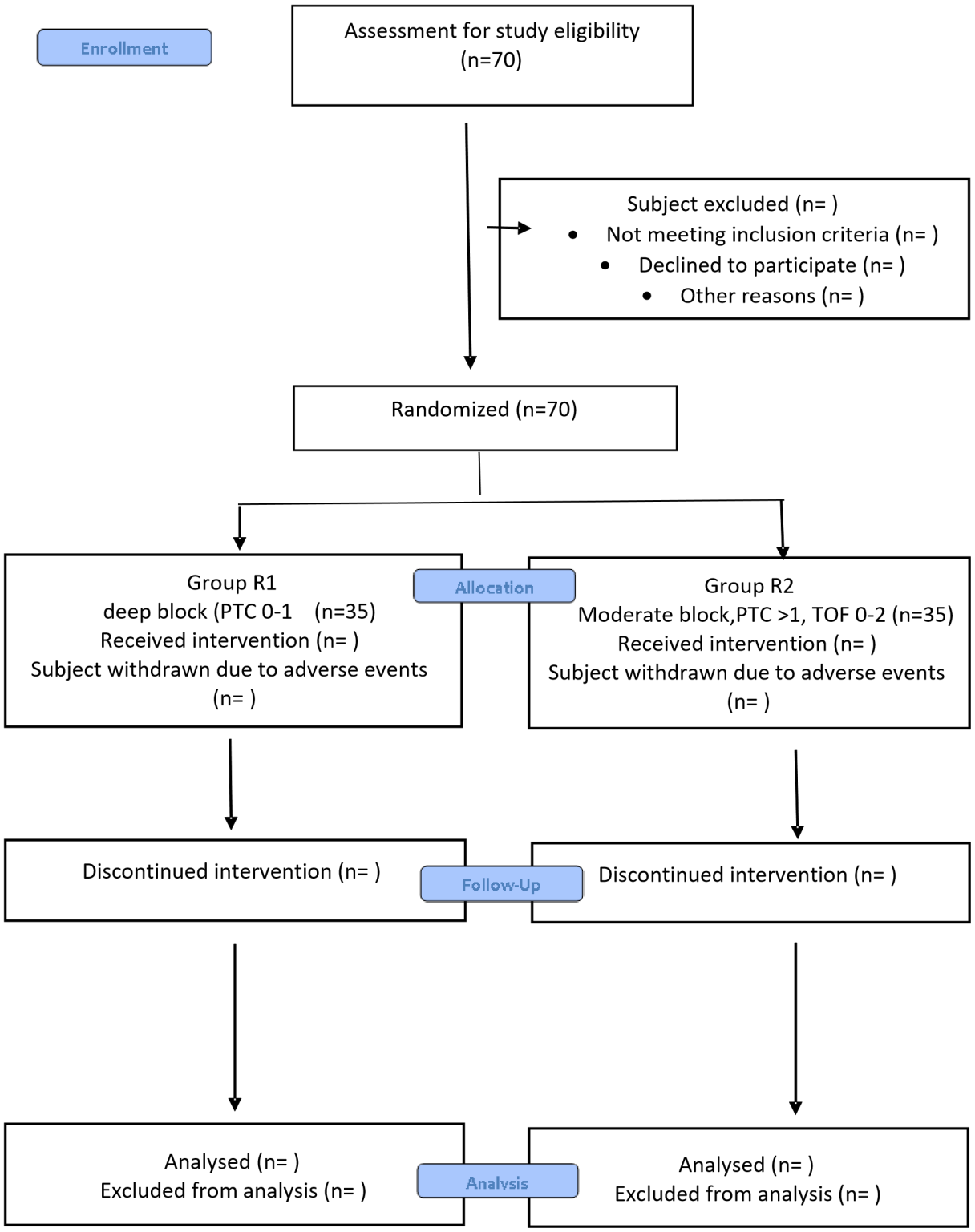
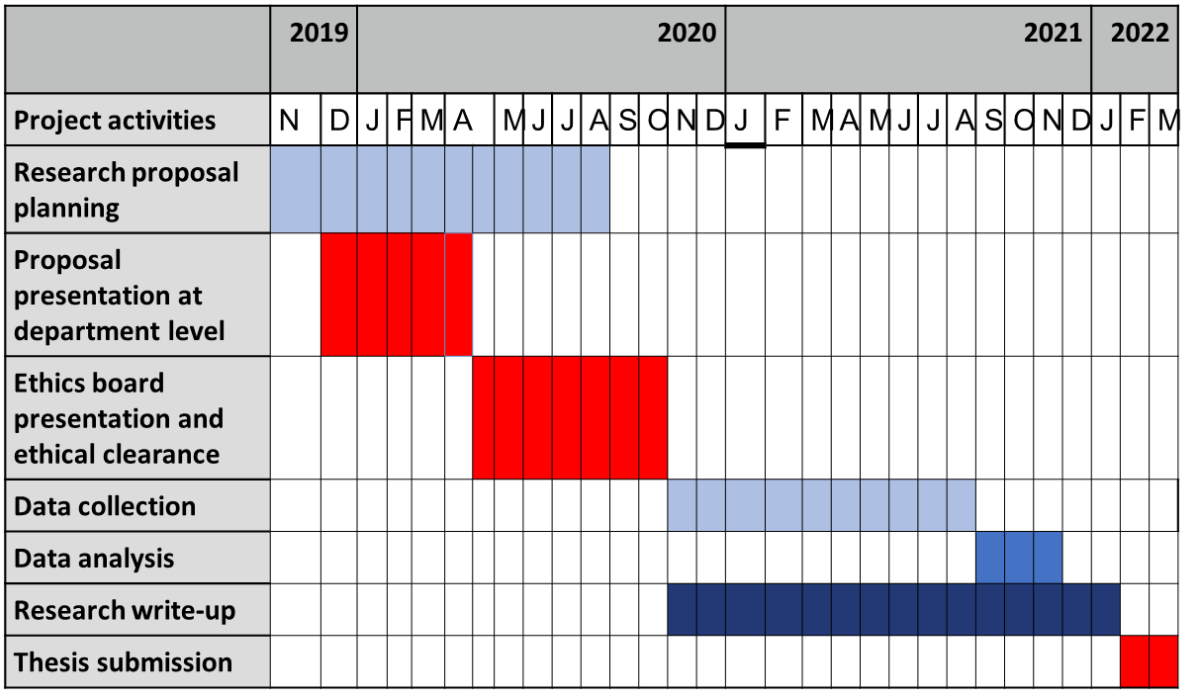


Dissertation write up and submission

Study flow chart according to CONSORT guideline



14- Gantt chart & milestone



15- Ethical consideration(s) [if applicable]:

The study will be conducted after obtaining ethics approval from Medical Research and Ethics Committee of University Sains Malaysia Health Campus.

A.Subject vulnerability:

- Potential study subjects are of ASA class I or II, who are not critically ill and require nonemergent, non-life saving surgeries whereby there is adequate time for patients counselling and study information. Study information and consent will be acquired during pre-operative round one day before operation. The potential subject is free to decide either to participate or not in the study after listen to all the explanation about the study. The patient schedule operation will be carried out as plan with all the standard procedure even the patient refuse to participate in the study.

- The study drug, sugammadex is proved to be saved in reversing deep neuromuscular block - The study drug is not administered for life saving or disease modifying purpose.

- Full information and the potential adverse effects of operation and study drug should be revealed.

- the study will be stopped immediately in case of adverse events and necessary treatment will be given.

-The investigator shall be blinded during the conduct of the study to eliminate potential bias and vulnerability issue. The investigator is investigator only, the other certified doctor will attend and conduct the case.

B. Declaration of absence of conflict of interest

- There is no conflict of interest in this study**.**

C. Privacy and Confidentiality

- Data obtained from this study did not identify the patient individually.

-The patient is ensured of full privacy and confidentiality and no personal information shall be revealed to other individuals except the investigators.

-Confidentiality shall only be broken if the study subject is suspected to have been harmeddirectly or indirectly by the study.

D. Community sensitivities and benefits

-Study drug and study procedures are provided at no cost to the patients involve.

-The potential benefit of the study includes reduce the side effect of pneumoperitoneum to cardiorespiratory system, reduce pain, and reduce patient satisfaction in the surgery.

E. Honorarium and incentives

-The participation in this study is entirely voluntary.

-There is no any kind of honorarium will be given to the subjects

- Patient may choose to withdraw patient from the study at any point without penalty or loss of benefits.

16- References

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3. KS G, JV, BR D. Low pressure versus standard pressure pneumoperitoneum in laparoscopic cholecystectomy. Cochrane Database Syst Rev 2014;3:1–6.

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11. Madsen, M.V., Gätke, M.R., Springborg, H.H., Rosenberg, J., Lund, J. And ISTRE, O. (2015), Optimised laparoscopic space. Acta Anaesthesiol Scand, 59: 441-447. doi:10.1111/aas.12493

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13. Dubois, Philippe E.; Putz, Laurie; Jamart, Jacques; Marotta, Maria-Laura; Gourdin, Maximilien; Donnez, Olivier Deep neuromuscular block improves surgical conditions during laparoscopic hysterectomy: A randomised controlled trial, European Journal of Anaesthesiology: August 2014 - Volume 31 - Issue 8 - p 430-436 doi: 10.1097/EJA.0000000000000094

14. Madsen, Matias V.; Istre, Olav; Staehr-Rye, Anne K.; Springborg, Henrik H.; Rosenberg, Jacob; Lund, Jørgen; Gätke, Mona R. Postoperative shoulder pain after laparoscopic hysterectomy with deep neuromuscular blockade and low-pressure pneumoperitoneum, European Journal of Anaesthesiology (EJA): May 2016 - Volume 33 - Issue 5 - p 341-347 doi: 10.1097/EJA.0000000000000360

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16. Park, Sun-Kyung; Son, Young G.; Yoo, Seokha; Lim, Taeyoon; Kim, Won Ho; Kim, Jin-Tae Deep vs. moderate neuromuscular blockade during laparoscopic surgery, European Journal of Anaesthesiology: November 2018 - Volume 35 - Issue 11 - p 867-875 doi: 10.1097/EJA.0000000000000884

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RESEARCH INFORMATION

Research title: **Research title: Evaluation of surgical condition during laparoscopic gynaecological surgery in patient with moderate vs deep neuromuscular block in lower pressure pneumoperitoneum.**

Principal investigator : **Dr Umairah Binti Esa (MMC 71514)**
Associate Prof Dr Rhendra Hardy B Mohamad Zaini (MMC 32241, NSR 126684).
Dr Zulfakar Mazlan (MMC 46464, NSR: 132658) Dr Sanihah Che Omar [MMC44833, NSR 132654] Dr Ahmad Akram Omar (MMC 46516, NSR 130133)

INTRODUCTION

Your are invited to participate in a voluntary research study on general anesthesia in laparoscopic surgery using the use of muscle relaxants at two different levels, both deep and moderate at low abdominal pressure during operation.

Before you participate in this study, it is important that you read and understand this research information. If you agree to participate in this study, you will receive a copy of this form for your records.

Your participation in this study is expected to take up to 24 hours after surgery. A total of 70 patients participated in this study. Your participation in this study is expected to last up to 24 hour after the completion of surgery. Up to 70 patients will be participating in this study.

PURPOSE OF THE STUDY

1. primary outcome variable was the rate of increasing intra-abdominal pressure (IAP) by the surgeon when they decided that the surgical conditions were inadequate for the operation in patient receiving deep and moderate neuromuscular block in laparoscopic gynaecological surgery.

2. To compare quality of surgical space condition in patient receiving deep and moderate neuromuscular block in laparoscopic gynaecological surgery.

3. To compare skin to sacral promontory distance in patient in patient receiving moderate neuromuscular block and deep neuromuscular block in laparoscopic gynaecological surgery.

4. To compare the post-operative pain and shoulder tip pain in patient receiving deep neuromuscular block and moderate neuromuscular block in laparoscopic gynaecological surgery

QUALIFICATION TO PARTICIPATE

The doctor in charge of this study or a member of the study staff have discussed with you the requirements for participation in this study. It is important that you are completely truthful with the doctor about your health history. You should not participate in this study if you do not meet all qualifications. You have your right to refuse to participate or to participate after listen to the procedure and study protocol. Your operation will still be carried out as plan if you refuse to participate in this study.

The requirements to be in this study are:

1. Age more than 18 years old
2. ASA I or II
3. schedule to undergo laparoscopic gynaecological surgery (laparoscopic hysterectomy and laparoscopic ovarian cystectomy in Hospital University Sains Malaysia , Kubang Kerian, Kelantan

Your cannot participate in this study if:

1. Allergy to study drugs (rocuronium, suggamadex)
2. Serious cardiac and respiratory disease (reactive airway disease, upper respiratory tract infection)
3. Neurological or neuromuscular disease (epilepsy, family history and history of malignant hyperthermia etc.)
4. Pregnancy
5. Morbid obesity BMI>35

STUDY PROCEDURE

Before the surgery, during premedication round we will tell you about this study. You will be asked to provide information about your medical history including all health problems, medical and surgical history, and any medications taken. You will also undergo a physical examination to ensure the suitability of this study.

After obtaining your consent, in the operating room, you will first be equipped with measuring and reading blood pressure, heart rate, heart rate, oxygen levels in the blood and levels of consciousness. This tool will record important readings throughout the anesthesia and surgery. Installation of these tools is a routine for all patients undergo anaethesia and surgery and you will be given general anesthesia on the day of surgery. Then you will receive standard general anesthesia like other surgical procedures. You will then be randomly assigned to one group, where one group will receive a moderate neuromuscular block, while another group will receive a deep neuromuscular block. This randomization is made using computer software.

Neuromuscular blockage is routine procedure during anaesthesia. Neuromuscular block is given to patient after the patient asleep under general anaethesia. In this study, neuromuscular block will be given in either deep neuromuscular block or moderate neuromuscular block and it will be strictly monitored with neuromuscular monitoring device. Deep neuromuscular block will cause the muscle to fully relax without contraction. After the operation finished neuromuscular blockade will be reverse by suggamadex. This medication is safe. The adverse event include allergic reaction and inadequate reversal but it is very rare.

Once the surgery is concluded, you will then be placed in the recovery area within the Operating Theater. You will be monitored for possible side effects of the study drug prior to transfer back to ward.

RISKS AND COMPLICATIONS

There are certain risks imposed to you with your participation in this research. Side effects that can occur including reduction in blood pressure and slow the heart rate, and risk of inadequate reversal cause breathing problems. Risk of deep neuromuscular blockage include inadequate reversal post operatively and there is a risk of shortness of breath. However this risk has been reduce by using neuromuscular monitoring and sugammadex. The endotracheal tube will only be removed after your muscle function recover completely. Risk of laparoscopic surgery include post operative nausea, vomiting, abdominal pain and shoulder tip pain.

Your will be closely monitored for occurrence of these side effects throughout the surgery and in recovery area post-surgery and will be promptly treated if present.

If any new information is found from this research which may affect your heath, you will be promptly notified.

Your safety is our priorities

REPORTING HEALTH EXPERIENCES

If you has any injury, adverse effects, or any unusual health experience(s) during this research, please inform immediately the nurse in charge or Dr. Umairah Esa (**MMC Registration No. 71514**) at 013-7517305. You can call at any time, day or night to report such health experience(s).

PARTICIPATION IN THE STUDY

Your participations in this research is entirely voluntary. You have the right to refuse participating in this research at any time, without any penalty or loss of benefits entitled to you. Your schedule operation will be going on as plan even if you refuse to participate in the research.

Your participation may also be stopped by the doctor in charge without your consent. If your were withdrawn from the research, the doctor in charge or personnel involve in the research will discuss with you regarding any possible medical issues related to your withdrawal from the research.

It will not involve any follow-up visit once you is discharged home

POTENTIAL BENEFITS

This drug used and procedures involved in this research will be provided to you at no cost. The outcome and information gained from this research may be beneficial to future patients. You will not receive any compensation for joining this research.

ENQUIRIES

If you have any enquiry about this research or on your rights as a participant, please contact:

Dr. Umairah binti Esa [MMC: 71514]
Jabatan Anaestesiologi dan Rawatan Rapi
USM Kampus Kesihatna
Tel. no: 013-7517305
Email: umairahesa@usm.my

ATAU

Assoc Prof Dr Rhendra Hardy Mohamad Zaini [MPM: 32241]
Dr zulfakar Mazlan [MMC 46464]
Dr Sanihah Che Omar [MMC44833]
Jabatan Anaestesiologi dan Rawatan Rapi
Dr Ahmad Akram Omar (MMC 46516, NSR 130133)
Jabatan Obstetri dan Gynaecology
USM Kampus Kesihatan
Email: rhendra@gmail.com/ zulfakar@usm.my/ sanihah_che@usm.my

If you have any questions regarding the Ethical Approval or any issue/problem related to this study, please contact;

En. Mohd Bazlan Hafidz Mukrim
Human Research Ethics Committee USM
Division of Research &Innovation (P&I)
USM Kampus Kesihatan.
No Tel: 09-7672354/ 09-7672362
Email: bazlan@usm.my/jepem@usm.my

OR

Miss Nor Amira Khurshid Ahmed

Secretariat of Human Research Ethics Committee USM Research Creativity & Management Office (RCMO) USM Main Campus, Penang
Tel. No. : 04-6536537 Email : noramira@usm.my CONFIDENTIALITY

Your medical information will be kept confidential by the research team. It will not be made publicity available unless its discussion is required by the law.

Data obtained from this research which does not identify you individually may be published for academic purposes.

Your original medical records may be reviewed by researcher, the Ethical Review Board for this research, and regulatory authorities for the purpose of verifying clinical trial procedures and / or clinical research data. Your medical records may be kept in and processed in a computer.

By signing this consent form, you authorize the record review, information storage and data transfer as describe above.

SIGNATURES

If you agree to take part in this research, you must sign the signature page

Patient Information and Consent Form
(Signature Page)

Research Title: Evaluation of surgical condition during laparoscopic gynaecological surgery in patient with moderate vs deep neuromuscular block in lower pressure pneumoperitoneum.

Principal investigator : Dr Umairah Binti Esa (MMC 71514)
Associate Prof Dr Rhendra Hardy B Mohamad Zaini (MMC 32241, NSR 126684).
Dr Zulfakar Mazlan (MMC 46464, NSR: 132658) Dr Sanihah Che Omar [MMC44833, NSR 132654] Dr Ahmad Akram Omar (MMC 46516, NSR 130133)

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Parents/Guardian Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree my child to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at any time.
- I have received a copy of this Parental/Guardian Information and Consent Form to keep for myself.

_____ _____

Patient's/Guardian's Name

_____ _____

Patient's/Guardian's I.C No. (New)

_____ _____

Signature of Patients/Guardian's Date (dd/MM/yy)

_____ _____

Name and Signature of Individual Conducting Consent Discussion Date (dd/MM/yy)

_____ _____

Name & signature of Witness Date (dd/MM/yy)

Note: i) All subjects/patients who are involved in this study will not be covered by insurance.

Participant's Material Publication Consent Form

Signature Page

Research Title: Evaluation of surgical condition during laparoscopic gynaecological surgery in patient with moderate vs deep neuromuscular block in lower pressure pneumoperitoneum.

Principal investigator : **DR UMAIRAH BINTI ESA (MMC 71514)**
Co-researchers: **ASSOCIATE PROF DR RHENDRA HARDY B MOHAMAD ZAINI (MMC 32241, NSR 126684).**
DR ZULFAKAR MAZLAN (MMC 46464, NSR: 132658)
DR SANIHAH CHE OMAR [MMC44833, NSR 132654]
DR AHMAD AKRAM OMAR (MMC 46516, NSR 130133)

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist worldwide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors worldwide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.
- The materials will not be used out of context – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

_____
Patient's/guardian name

_____ _____
Patientt's/Guardian's I.C No. (New)

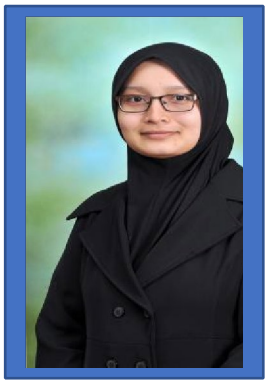
_____

_____
Signature of Patient /Guardian's Date (dd/MM/yy)

Name and signature of Individual Conducting Consent Discussion	Date (dd/MM/yy)

Note: i) All subjects/patients who are involved in this study will not be covered by insurance.

CURRICULUM VITAE



1. **Name:** Dr. Umairah binti Esa

2. **I. C. No./Passport No.:** 890301015108

3. **Work Address:** Department of Anaesthesiology,
School of Medical Sciences,
Health Campus,
Universiti Sains Malaysia.,
16150 Kubang Kerian,
Kelantan
Tel. No: 0137517305
E-mail Address: umairahesa@usm.my

4. **Academic Qualifications and Brief Career History:**

Year	Degree	Discipline	University
2008-2014	Bachelor in Medicine and Bachelor in Surgery (MBBS)	Medicine	Universiti Sains Islam Malaysia
2018-present (in training)	Master in Medicine	Anaesthesiology	Universiti Sains Malaysia

Year	Position	Place of Work
2014-2017	House Officer	Hospital Sultanah Nora Ismail Jalan Korma, Taman Soga, 83000 Batu Pahat, Johor
2017-2017	Medical Officer	Department of Anaesthesiology and Intensive Care, Hospital Melaka Jalan Mufti Haji Khalil 75400 Melaka
2017-2018	Medical officer	Department of Anaesthesiology and Intesive Care, School of Medical Science, Health Campus Universiti Sains Malaysia
2018-present	Master Student	Department of Anaesthesiology and Intesive Care, School of Medical Science, Health Campus Universiti Sains Malaysia

CURRICULUM VITAE

Name: Assoc. Prof. Rhendra Hardy Bin Mohamad Zaini

2. I. C. No./Passport No: 701215-03-5358

3. Work Address: Department of Anaesthesiology
School of Medical Science, Health Campus,
Universiti Sains Malaysia,
16150 Kubang Kerian, Kelantan

Tel. No: +6097676095
Fax No: +6097653370
Mobile Phone No: +60199106665
E-mail Address: rhendra@gmail.com

4. Academic Qualifications and Brief Career History:

Year	Degree	Discipline	University
1995	Medical Degree	Medicine	USM
2002	Master in Medicine	Anaesthesiology	USM
2005	Fellowship	Pain and Thoracic Anaesthesia	Toranomon Hospital, Tokyo, Japan

Year	Position	Place of work
1995-1996	House Officer	Hospital Kota Bharu, Hospital Alor Setar
1996-1998	Medical Officer	Dept of Anaesthesiology, USM
2000-2002	Trainee Lecturer	Dept of Anaesthesiology, PPSP, USM
2002-present	Lecturer & Anaesthesiologist	Dept of Anaesthesiology, PPSP, USM

5.Field(s) of Specialization: Airway management

6.Research area:

- Airway management
- Regional anaesthesia
- Nutrition in ICU

7. Grants in the Last 5 Years:

1. Comparing the Effectiveness Between Air-Q Intubating Laryngeal Airway and Ambu® AuraGain™ Laryngeal Mask as a Conduit for Endotracheal Intubation in Simulated Cervical Spine Injury in Adult.

2. Comparative Study on Sustainable Monitoring During Total Intravenous Anaesthesia in Neurosurgery between Bispectral Index and Cerebral State Monitoring (2017-2019). Short term Grant, RM 37,440. Mohamad Hasyizan Bin Hassan, **Rhendra Hardy Mohd Zaini**,

8. List NOT MORE than 10 Significant/Relevant/Related Journal Publications:

1. Mohd Hasyizan H., Wan Mohd Nazaruddin W. H., **Rhendra Hardy M. Z**., Wan Fadzlina W. M. S., Huda Z. A., Chong S. E. Balanced Fluid Versus Saline-Based Fluid in Post-operative Severe Traumatic Brain Injury Patients: Acid-Base and Electrolytes Assessment. Malaysian Journal of Medical Sciences; 24(5): 83-93. Index in: Bioline International, SCOPUS, EBSCO, DOAJ, Index Copernicus, Google Scholar,MyAIS.2017, 24/5: 83-93.

2. Wan Hassan WMN, Suut N, Tan PCH, **Mohd Zaini RH**. Balanced versus Saline-Based Fluid Regimen for Elective Supratentorial Craniotomy: Acid-Base and Electrolyte Changes. Middle East Journal of Anaesthesiology, Oct 2017, 24(3); 195-204. Index in: the Index Medicus and MEDLARS system, SCOPUS. ISSN 0544-0440

3. Wan Hassan WMN, Mohd Nasir Y, **Mohd Zaini RH**, Wan Ahmad Shukeri WF. Target-controlled Infusion Propofol versus Sevoflurane Anaesthesia for Emergency Traumatic Brain Surgery: Comparison of the Outcomes. Malaysian Journal of Medical Sciences, 2017; 24(2):73-82. Index in: Bioline International, SCOPUS, EBSCO, DOAJ, Index Copernicus, Google Scholar, MyAIS

4. Wan Hassan WMN, Tan HS, **Mohd Zaini RH**. Comparison of the effects of dexmedetomidine on induction between using Marsh and Schnider pharmacokinetic models of propofol targetcontrolled infusion. Malaysian Journal of Medical Sciences Jan-Feb 2018, 25 (1): 24-31. Index in: Bioline International, SCOPUS, EBSCO, DOAJ, Index Copernicus, Google Scholar, MyAIS

5. Mohamad Hasyizan Bin Hassan, Fung EM, **Rhendra Hardy Mohd Zaini**, Shamsul kamalrujan Hassan, S Praveena A/p Seevaunnamtum, Mohd Zulfakar Bin Mazlan A Comparison Between Measured Maxillopharyngeal Angle On Lateral Cervical Radiograph With Modified Mallampati Classification In Predicting Difficult Larnygoscopy : A Blinded Interventional Study. Malaysian Journal of Medicine and Health Science. 2018;14(2); 51-56. Indexed in: Scopus, EBSCOhost, ISC, and Rubriq

6. Chong Soon Eu, **Rhendra Hardy Mohd Zaini**, Wan Fadzlina Binti Wan Muhd Shukeri, Al-jadidi Bin Sulaiman, Vivekananda Gunasekaran. Sugammadex Rescue in Avoiding Intensive Care Unit Admission in an Octogenarian Undergoing Emergency Laparotomy. Journal of PeriAnesthesia Nursing, 2018; 33/5:, 727-731. Indexed in CINAHL and Scopus.(Impact Factor : 0.748)

7. Mohd Zulfakar Bin Mazlan, Nik Abdullah Bin Nik Mohamad, Zeti Norfidiyati Binti Salmuna@ayub, Mohamad Hasyizan Bin Hassan, Saedah Binti Ali, W Mohd Nazaruddin Bin W Hassan, Laila Binti Ab Mukmin, **Rhendra Hardy Mohd Zaini**, Ariffin Marzuki Bin Mokhtar, Chandran A/l Nadarajan, Ahmad Zuhdi Bin Mamat, Alwi Bin Muhd Besari @ Hashim, Azian Binti Harun. A Fatal Case of Immunocompetent Aspergilloma: Bronchial Artery Embolization Fail to Halt Recurrent Hemoptysis. Current Respiratory Medicine Reviews, 2018, 14:1-3. Index in: Emerging Sources Citation Index (ESCI), Scopus, EMBASE, Chemical Abstracts Service/SciFinder, ProQuest, ChemWeb, Google Scholar, CINAHL®, EMNursing, PubsHub, Index Copernicus, Genamics JournalSeek, MediaFinder®-Standard Periodical Directory, J-Gate, CNKI Scholar, Suweco CZ, TOC Premier, EBSCO, Ulrich's Periodicals Directory and JournalTOCs. (Impact Factor : 0.13)

8. Wan Mohd Nazaruddin Wan Hassan, Azelia Mansur, Rhendra Hardy Mohamad Zaini.Anaesthesia using target-controlled infusion of Propofol during pediatric surgery: Kataria

versus Paedfussor pharmacokinetic. Anaesthesia, Pain and Intensive Care, 2018 22(2):207-211. Index in: Embase, EMCare,Index Medicus (EMR), Ulrich's Directory (Switzerland), UDL (Malaysia), infomine – The Regents of the University of California, GFMER – Geneva, Foundation for Medical Education and Research, Index Pakistan of PM&DC approved journals, EZB – Electronic Journals Library,JournalSeek, SCIRUS, I-Share , University of Newcastle, ISSN:1607-8322 (Print) ; 2220-5799 (Electronic) ; 1607-8322 (Linking)

9. Wan Fadzlina Wan Muhd Shukeri, Mohd Hasyizan Hassan, Wan Mohd nazaruddin WanHassan, **Rhendra hardy Mohamad Zaini**. Anastomotic Leak after Bariatric Surgery from a Critical Care Perspective: A Lesson Shared. Malays J Med Sci.; 2018 25(5): 157–158.Index in: Bioline International, SCOPUS, EBSCO, DOAJ, Index Copernicus, Google Scholar, MyAIS

10. Nirawanti Mohamad Said, **Rhendra Hardy Mohd Zaini** (*Corresponding author), W Mohd Nazaruddin Bin W Hassan, Mohamad Ibariyah Bin Iberahim, Chong Soon Eu. A Randomized Comparison of the Air-Q Intubating Laryngeal Airway and Ambu®AuraGain™ Laryngeal Mask for Controlled Ventilation in Children. Anaesthesia, Pain and Intensive Care, 2018 (Accepted)

CURRICULUM VITAE

1. **Name:** Dr Mohd Zulfakar bin Mazlan

2. **I. C. No./Passport No.:** 821124145833

3. **Work Address:**

Department of Anaesthesiology
School of Medical Science, Health Campus,
Universiti Sains Malaysia,
16150 Kubang Kerian, Kelantan

Tel. No: 097676104

Fax No: 097653350

Mobile Phone No: 0129091447

E-mail Address: zulfakar@usm.my, zulfakarmohd98@yahoo.com

4. **Academic Qualifications and Brief Career History:**

Year	Degree	Discipline	University/Work Place
2007	MBBS (MPM 46464)	Medical Doctor	International Islamic University Malaysia
2015	MMed (NSR132658)	Anaesthesiology	Universiti Sains Malaysia

5. **Field(s) of Specialization:** Anaesthesiology and Critical Care

6. **Research Area: Anaesthesiology and Critical Care**

7. **Grants in the Last 5 Years: Short term USM grant 2016 as a Leader (PI at USM), FRGS 2016 as a Co- Researcher (PI at USM site), PRGS 2018 as a Co- Researcher**

8. **List NOT MORE than 10 Significant/Relevant/Related Journal Publications:**

1-Mohd Zulfakar Bin Mazlan, Shamsul Kamalrujan Hassan, Laila Binti Ab Mukmin, Mohamad Hasyizan Bin Hassan, Huda Binti Zainal Abidin, Irfan Bin Mohamad, Chandran A/l Nadarajan, Rubindetan Muthusamy, Chong Soon Eu, 2016, Novel Usage of Dexmetomidine In A Paediatric Patient With Giant Tongue Haemangioma,Malaysian Journal of Medicine and Health Sciences: , Impact Factor : 0.1

2- Mohd Zulfakar Bin Mazlan, Rhendra Hardy Mohd Zaini, Shamsul Kamalrujan Hassan, Saedah Binti Ali, Sanihah Binti Che Omar, W Mohd Nazaruddin Bin W Hassan, 2017, Significance of a clean-tip catheter closed suctioning system in a high-setting ventilated, super morbidly obese patient with profuse respiratory secretions, Respiratory Medicine Case Reports, 21(2017)129-131:, (Impact Factor : 0.2)

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6- Nazhan Afeef Mohd Ariff, Mohd Zulfakar Bin Mazlan, Mohd Erham Bin Mat Hassan, S Praveena A/p Seevaunnamtum, Wan Fadzlina Binti Wan Muhd Shukeri, Nik Abdullah Bin Nik Mohamad, Shamsul Kamalrujan Hassan, Kamaruddin Jaalam, Mohamad Hasyizan Bin Hassan, Sanihah Binti Che Omar, Chandran A/l Nadarajan, Irfan Bin Mohamad, 2018, Undiagnosed chicken meat aspiration as a cause of difficult-to-ventilate in a boy with traumatic brain injury, Respiratory Medicine Case Reports, :, (Impact Factor : 0.2)

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8- Mohd Zulfakar Bin Mazlan, Nik Abdullah Bin Nik Mohamad, Zeti Norfidiyati Binti Salmuna@ayub, Mohamad Hasyizan Bin Hassan, Saedah Binti Ali, W Mohd Nazaruddin Bin W Hassan, Laila Binti Ab Mukmin, Rhendra Hardy Mohd Zaini, Ariffin Marzuki Bin Mokhtar, Chandran A/l Nadarajan, Ahmad Zuhdi Bin Mamat, Alwi Bin Muhd Besari @ Hashim, Azian Binti Harun, 2018, A Fatal Case of Immunocompetent Aspergilloma: Bronchial Artery Embolization Fail to Halt Recurrent Hemoptysis, Current Respiratory Medicine Reviews,, 14,:, 1-3 (Impact Factor : 0.13)

9-Mohamad Hasyizan Bin Hassan, Rhendra Hardy Mohd Zaini, Shamsul Kamalrujan Hassan, S Praveena A/p Seevaunnamtum, Mohd Zulfakar Bin Mazlan, Nik Abdullah Bin Nik Mohamad, 2018, A Comparison Between Measured Maxillopharyngeal Angle On Lateral Cervical Radiograph with Modified Mallampati Classification In Predicting Difficult Larnygoscopy: A Blinded Interventional Study, Malaysian Journal of Medicine and Health Sciences, 14(2):, 51-56 (Impact Factor : 0.107)

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CURRICULUM VITAE

1. **Name: DR AHMAD AKRAM OMAR**

2. **Work Address:** Department of Obstetric and Gynaecology,
School of Medical Sciences,
Health Campus,
Universiti Sains Malaysia.,
16150 Kubang Kerian, Kelantan
Tel. No: 0179817277
E-mail Address: drakram@usm.my

3. **Academic Qualifications and Brief Career History:**

Year	Degree	Discipline	University
1997-2002	Medical Degree	Medicine	Universiti Sains Malaysia
2007-2011	Master in Medicine	Obstetrics & Gynaecology	Universiti Sains Malaysia
2015-2016	Clinical Fellowship	The Asia Pacific Association for Gynaecologic Endoscopy and Minimally Invasive Therapy, Chang Gung Memorial Hospital, Taiwan	

Year	Position	Place of Work
2002-2003	House Officer	Hospital Universiti Sains Malaysia
2003-2004	Medical Officer	Hospital Raja Perempuan Zainab II
2004-2006	Medical officer	Hospital Kuala Krai
2006-2010	Trainee lecturer O&G	School of Medical Science, Health Campus Universiti Sains Malaysia

2011-present	Lecturer and Consultant Obstetric and Gynaecology	Hospital Universiti Sains Malaysia
2014	Clinical attachment in Minimally Invasive Surgery	Hospital Putrajaya

4. **Field(s) of Specialization:** Obstretric and Gynaecology

5. **Research Area:** Minimally Invasive Gynaecology Surgery (MIGS)
Fertility and Reproductive Health

6. **Grants in the Last 5 Years:** Incentive Grant USM 2019 -2020 AR Gynae Endotrainer
Innovation Grant USM

7. **List NOT MORE than 10 Significant/Relevant/Related Journal Publications**

1. Hoo PS, Afendi NR, Mahamooth MIJ, Ismail AA, Rahim RA, Omar AA. Review of a case of choriocarcinoma with vaginal metastases. Edorium J Gynecol Obstet 2016;2:48-51.2.
2. Hoo PS, Afendi NR, Yeng LW, Yahaya AS, Ismail AA, Rahim RA, Omar AA, Ismail MP. Treat secondary amenorrhea by oophorectomy: A case of adult granulosa cell tumour with pseudo- FSH deficiency manifested by secondary amenorrhea. Edorium J Gynecol Obstet 2017;3:1-4.
3. Afendi NR, Hoo PS, Ismail AA, Rahim RA,Omar AA, Ibrahim A.Coexistance of Mayer-Rokistansky-Kuster-Hauser syndrome with Turner syndrome: A case report. *Edorium J Gynecol Obstet* 2017;3,5-8.
4. Omar AA, Othman MS, Hoo PS, Zon EM, Ismail AA, Rahim R, Afendi NR, Ibrahim A. Menstruation from the pfannensteil scar: A case of rare presentation of atypical endometriosis. Edorium J Gynecol Obstet 2017;3:1-4
5. A.A Omar, M.S Othman, H.P Sung, E.M Zon, A.A Ismail, R. Rahim, N.R.N.M Afendi, A. Ibrahim, 2018, Menstruation from the pfannensteil scar: A case of rare presentation of atypical endometriosis, Journal of case reports and images in Obstetric and Gynaecology, 4/2018:, 1-4
6. Rahimah abdul rahim, ahmad amir ismail, nik rafiza nik afendi, ahmad akram omar, adibah ibrahim, erinna mohamad zon, Shah Reza Johan Noor, Munirah Aminullah, 2020, A 5-year review of seminal fluid analysis in Hospital Universiti Sains Malaysia, Kubang Kerian, Brunei International Medical Journal,
7. Ahmad amir ismail, rahimah abdul rahim, ahmad akram omar, nik rafiza nik afendi, Hoo Pek Sung, mohd pazudin ismail, Wan
8. Fadhlina Wan Adnan, Engku Husna Engku Ismail, Syamilah Mokhtar, 2020, Urinary tract infection following urodynamic study in Hospital Universiti Sains Malaysia, Kelantan, Brunei International Medical Journal,
9. Ahmad Akram Bin Omar, Erinna Binti Mohamad Zon, Adibah Binti Ibrahim, 2020,

Spontaneous severe ovarian hyperstimulation syndrome in a singleton pregnancy, BMJ Case Reports

10. Ahmad Akram Bin Omar, Adibah Binti Ibrahim, 2020, Partial mole with coexisting fetus presented with hyperemesis gravidarum and hyperthyroidism: a case presentation, Taiwanese Journal of Obstetrics and Gynaecology,

Certification OF Participation

This is to certify that

Dr. Rhendra Hardy Mohamad Zaini

has succesfully completed

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DATO' DR. ISMAIL MERICAN
Deputy Director General of Health (R & TS)
Ministry of Health Malaysia

ASSOC. PROF. ABD. RASHID ABD. RAHMAN
Coordinator
Clinical Trial Unit
School of Medical Sciences
Universiti Sains Malaysia

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan
16150 Kubang Kerian, Kelantan. Malaysia.
Tel. : +609 - 767 3000/2354/2362
Fax. : +609 - 767 2351
Email : jepem@usm.my
Laman Web : www.jepem.kk.usm.my
www.usm.my

13th December 2020

Dr. Umairah Esa
Department of Anaesthesiology
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/20080410
Protocol Title : Evaluation of Surgical Condition during Laparoscopic Gynaecological Surgery in Patient with Moderate vs Deep Neuromuscular Block in Lower Pressure Pneumoperitoneum.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/20080410**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **13th December 2020** until **12th December 2021.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:
1. Assoc. Prof. Dr. Rhendra Hardy Mohd Zaini
2. Dr. Mohd Zulfakar Mazlan
3. Dr. Sanihah Che Omar

The following documents have been approved for use in the study.
1. Research Proposal

In addition to the abovementioned documents, the following technical documents were included in the review on which this approval was based:
1. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Data Collection Form

The list of JEPeM-USM members present during the full board meeting reviewing your protocol is attached.

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.**
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**

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JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,

ASSOC. PROF. DR. AZLAN HUSIN
Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia
Kampus Kesihatan
16150 Kubang Kerian, Kelantan, Malaysia.
Tel. : +609 - 767 3000/2354/2362
Fax. : +609 - 767 2351
Email : jepem@usm.my
Laman Web : www.jepem.kk.usm.my
www.usm.my

9th March 2021

Dr. Umairah Esa
Department of Anaesthesiology
School of Medical Sciences
Universiti Sains Malaysia
16150, Kubang Kerian, Kelantan.

JEPeM USM Code: USM/JEPeM/20080410

Study Protocol Title: Evaluation of Surgical Condition during Laparoscopic Gynaecological Surgery in Patient with Moderate vs Deep Neuromuscular Block in Lower Pressure Pneumoperitoneum.

Dear Dr:

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) approved the proposed amendments in your study entitled, **"Evaluation of Surgical Condition during Laparoscopic Gynaecological Surgery in Patient with Moderate vs Deep Neuromuscular Block in Lower Pressure Pneumoperitoneum" [USM/JEPeM/20080410]**

Upon review of JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form, the following amendments have been approved:

1. Add Co-Researcher – Dr. Ahmad Akram Omar

Thank you.

Sincerely,

PROF. DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

c.c Secretary
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia