1. Study Identification

Unique Protocol identification Number:
KB/106/2018

Brief Title:
Dural tenting sutures in neurosurgery - is it necessary?

Official Title:
Prophylactic use of dural tenting sutures in elective craniotomies - is it necessary? A multicentre randomised study.

Acronym:

Study Type:
Interventional

2. STUDY STATUS

Record Verification Date:
June 2018

Overall Recruitment Status:
Recruiting

Study Start Date:
September 7, 2018

Primary Completion Date:
Anticipated September 1, 2021

Study Completion Date:
Anticipated April 1, 2022

3. SPONSOR/COLLABORATORS

Responsible Party, by Official Title:
Sponsor

Investigator Information:

Investigator Name:
Przemysław Kunert

PG. 1
4. OVERSIGHT

Studies a U.S. FDA-regulated Drug Product:
No

Studies a U.S. FDA-regulated Device Product:
No

Device Product Not Approved or Cleared by U.S. FDA:
No

Post Prior US FDA Approval or Clearance:
No

Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information:

U.S. Food and Drug Administration IND or IDE:
No

Human Subjects Review:

Human Subjects Protection Review Board Status:
Submitted, approved

Board Approval Number:
KB / 106 / 2018

Board Name:
Komisja Bioetyczna przy Warszawskim Uniwersytecie Medycznym
(Bioetics Comitee, Medical University of Warsaw)
5. STUDY DESCRIPTION

Brief Summary (using lay language): This study evaluates the necessity of dural tenting sutures in craniotomies. The sutures elevate the dura, a layer between the brain and skull. Supposedly, by doing so, they prevent blood collecting between dura mater and the skull. These blood collections, called epidural hematomas, contributed greatly to postoperative mortality in the early days of neurosurgery. There have been several reports questioning the ongoing need for them in neurosurgery, thanks to modern hemostatic techniques. Moreover, it has been published in the literature, and is a common knowledge as well, that some neurosurgeons do not use these sutures at all, and do not have worse outcomes than their colleagues.

In this study, half of the randomly assigned participants will undergo craniotomy without dural tenting sutures and will be considered an intervention group. The other half will undergo craniotomy with these sutures.

Detailed Description:

In the early days of neurosurgery, epidural hemorrhages (EDH) contributed to a high mortality rate after craniotomies. Almost a century ago Walter Dandy reported dural tenting sutures as an effective way of preventing postoperative EDH. Over time, his technique gained in popularity and significance to finally become a neurosurgical standard.

Yet, there have been several retrospective reports questioning the ongoing need for dural tenting sutures. Dandy’s explanation that the hemostasis under hypotensive conditions is deceiving and eventually causes EDH may be obsolete. These days, proper intra- and postoperative care, including maintenance of normovolemia and normotension and the use of modern hemostatic agents, may be enough for effective hemostasis. Evading of this suturing technique by some surgeons supports this argument even further.

Thus, there is a fundamental need to evaluate the necessity of dural tenting sutures in an unbiased, evidence-based manner.
6. CONDITIONS AND KEYWORDS

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study:

1. Epidural Hematoma

Keywords:

1. Craniotomy
2. Dural Tenting Suture
3. Epidural Hematoma

7. STUDY DESIGN (INTERVENTIONAL)

Primary purpose:

Prevention

Study Phase:

N/A

Interventional Study Model:

Parallel

Model Description:

We plan to include 2000 subjects in this study. Each subject will undergo a craniotomy for unrelated pathology. Each of the subjects will be assigned in random order to an intervention or control group. The intervention group will not have dural tenting sutures during closure of their craniotomy while the control group will have at least three.

Both groups will be followed radiologically and clinically, in the exact same manner.

Number of Arms:

2

Masking Roles, if Masking:

Participant
Investigator
Outcomes Assessor

Masking Description:

Due to the nature of the surgical procedures, the surgeon and the rest of the OR medical team will be aware of the current subject’s allocation. However, in each case, the specific OR team aware of the subject’s allocation will be different from the investigators performing further evaluation of the given subject. The following study procedures will be in place to ensure double-blind administration of the study.

- Access to the randomization code will be strictly controlled.
- The surgeon will receive information on subject’s allocation after commencing the surgery.

The study blind will be broken:

1. During interim monitoring, after recruiting the first 100 patients.
2. On completion of the clinical study and after the study database has been locked.

3. When patients’ safety requires access to allocation data.

**Allocation:**

*Randomized*

**Enrollment Type:**

*Anticipated*

**Number of Participants:**

2,000

8. ARMS, GROUPS, AND INTERVENTIONS

**Arm 1:**

**Arm Type:**

*No intervention*

**Arm Title:**

*No dural tenting sutures*

**Arm Description:**

*No dural tenting techniques*

**Arm 2:**

**Arm Type:**

*Active Comparator*

**Arm Title:**

*Dural tenting sutures*

**Arm Description:**

*Dural tenting techniques*

**Intervention 1:**

**Intervention Type:**

*Procedure/Surgery*

**Intervention Name**

*No dural tenting techniques*

**Other Intervention Name 1:**

*No tack-up sutures*

**Other Intervention Name 2:**

*No hitch-up stitches*
**Intervention Description:**

Not applying dural tenting sutures during closure of a craniotomy

**Intervention Type:**

Procedure/Surgery

**Intervention Name**

Dural tenting techniques

Other Intervention Name 1:

No tack-up sutures

Other Intervention Name 2:

No hitch-up stitches

**Intervention Description:**

Applying at least 3 dural tenting sutures during closure of a craniotomy in a usual way

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### Arm/Interventional Cross–Reference

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### 9. OUTCOME MEASURES

**Outcome 1:**

**Primary Outcome Measure:**

**Title:**

Reoperation due to epidural hematoma

**Description:**

Percentage

**Time Frame:**

During hospitalization for the surgery, approximately 2 days postoperatively

**Outcome 2:**

**Secondary Outcome Measure:**

**Title:**

Postoperative 30-day mortality

**Description:**

Percentage

**Time Frame:**

30-day postoperatively
Outcome 3:
Secondary Outcome Measure:
Title:
Postoperative 30-day readmission to a neurosurgical or neurological department
Description:
Percentage
Time Frame:
30-day postoperatively

Outcome 4:
Secondary Outcome Measure:
Title:
New neurologic deficit or deterioration of a previous one
Description:
Specific description of a neurologic deficit
Time Frame:
During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if the patient is discharged before the fifth postsurgical day.

Outcome 5:
Secondary Outcome Measure:
Title:
Cerebrospinal fluid leak requiring treatment
Description:
Percentage
Time Frame:
During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if the patient is discharged before the fifth postsurgical day.

Outcome 6:
Secondary Outcome Measure:
Title:
Deterioration of postoperative headaches over 5 in Numerical Rating Scale
Description:
The Numeric Rating Scale is an 11-point scale for patient self-reporting of pain. It ranges from 0 (no pain) to 10 (the worst imaginable pain). There are no subscales. Higher values indicate more pain and, therefore, represent undesirable outcome.
Time Frame:
During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if
the patient is discharged before the fifth postsurgical day.

Outcome 7:
Secondary Outcome Measure:
Title: Epidural collection thickness over 3 mm measured radiographically
Description: The thickness of the epidural collection measured in a postoperative CT scan
Time Frame: During hospitalization, approximately 1-3 days postoperatively

Outcome 8:
Secondary Outcome Measure:
Title: Midline shift over 5 mm
Description: Midline shift caused by the epidural collection measured in a postoperative CT scan
Time Frame: During hospitalization, approximately 1-3 days postoperatively

10. ELIGIBILITY

Sex/Gender:
Sex: All
Gender-Based: No

Age Limits:
Minimum Age: 18
Unit of Time: Years
Maximum Age: 75
Unit of Time: Years

Accepts Healthy Volunteers: No

Eligibility Criteria:
Inclusion Criteria:
- Male or female over 18 and under 75 years old
- Qualified for an elective supratentorial craniotomy with a diameter of at least 3 cm
- Glasgow Coma Scale 15 preoperatively
- Modified Rankin Scale 0, 1 or 2 preoperatively

Exclusion Criteria:
- Coagulation abnormalities before the surgery
- Revision craniotomy
- Skull base surgery

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

Central Contact Person:
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Degree:
Organization/Affiliation: Department of Neurosurgery, Medical University of Warsaw
Official’s Role: study principal investigator

Overall Study Official 2:

First Name: Przemysław
Last Name or Official Title: Kunert
Degree: MD, PhD
Organization/Affiliation: Department of Neurosurgery, Medical University of Warsaw
Official’s Role: study principal investigator

Facility Information:

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State/Province: Mazovian
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Facility Information

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Country: Poland
Individual Site Status:
Recruiting

Facility contact:

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Phone: +48 42 677 67 82
Email:

Facility Contact Backup:

First name:
Last Name:
Degree:
Phone:
Email:

Facility Information:

Facility Name: Department of Neurosurgery, Medical University of Silesia, Regional Hospital, Sosnowiec
City: Sosnowiec
State/Province: Śląskie
ZIP/Postal Code: 41-200
Country: Poland
Individual Site Status:

**Recruiting**

Facility contact:

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<tr>
<th>First Name</th>
<th>Piotr</th>
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<tr>
<td>Last Name or Official Title:</td>
<td>Ładziński</td>
</tr>
<tr>
<td>Degree</td>
<td>MD, PhD</td>
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<tr>
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Facility Contact Backup:

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Facility Information:

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<th>Facility Name:</th>
<th>Neurosurgery and Pediatric Neurosurgery Department in Lublin, Medical University of Lublin, Lublin, Poland</th>
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ZIP/Postal Code: 20-954
Country: Poland
Individual Site Status: Recruiting

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Degree: MD, PhD
Phone:
Email:

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State/Province:
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Country: Poland

Individual Site Status: Recruiting

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Facility Principal Investigator:
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Last Name: Harat
Degree: MD, PhD
Phone:
Email:

Facility Information:
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Country: Poland

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Facility Principal Investigator:
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12. IPD SHARING STATEMENT

Plan to Share IPD:
- No

IPD Sharing Plan Description:

IPD Sharing Supporting Information Type:

IPD Sharing Time Frame:

IPD Sharing Access Criteria:

IPD Sharing URL:

13. REFERENCES

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<td>Swayne OB, Horner BM, Dorward NL. The hitch stitch: an obsolete neurosurgical technique? Br J Neurosurg. 2002 Dec;16(6):541-4; discussion 544.</td>
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