

**NCT02990910**

**The effect of individualized analgesia  
on respiratory adverse events after  
adenotonsillectomy in Children  
—randomized double-blind controlled trial**

**2017-2-15**

# Informed Consent Form

Research name: The effect of individualized analgesia on respiratory adverse events after adenotonsillectomy in Children—randomized double-blind controlled trial

Project leader: Wang Xuan Phone : 18017591058

The children's Hospital of Fudan University

You are invited to participate in this project. This notification provides information about this study to know. If you agree to participate, you will be asked to sign the informed notice.

## **1. Research purpose**

The aim of this study was to verify the hypothesis that individualized opioid analgesia regimen according to fentanyl test could decrease the incidence of postoperative respiratory adverse events and improve the effect of analgesia compared with conventional opioid analgesia regimen after adenotonsillectomy in children.

## **2. Research programme**

In this prospective, double-blind, randomized, controlled clinical trial, 280 children scheduled for adenotonsillectomy under general anesthesia at the Children's Hospital of Fudan University from November 2016 through February 2017 were selected. If your child decides to participate in this study you will need to take about 10 minutes of preoperative

interview. You will be asked about their children at night and if daily respiratory abnormalities. Preoperative random allocation group is based on the analgesia of fentanyl in postoperative test individual, according to conventional methods of analgesia in the control group. Pain management in the recovery room, has a dedicated staff of child's pain scores, according to the grouping and scoring intravenous morphine analgesia, compared between the two groups the incidence of adverse respiratory events. When pain scores and Aldrete score was reached, the children will be sent back to the ward.

### **3. Possible risks**

And like a regular check, data collection may have some risks, including recurrent laryngeal spasms, nausea, vomiting, aspiration, and so on. If these conditions occur, will be processed in a timely manner.

### **4. Possible benefits**

You will receive regular follow-up of our health, and are ready to provide you with health and treatment of nocturnal sleep respiratory disorder syndromes in children information and advice.

### **5. Research related injury compensation and treatment**

We will carefully assess your damage as a result of the study, and provide the proper treatment in order to preserve your rights. Fudan University children's Hospital anesthesia Department will provide you with insurance, if there is damage

due to studies, Fudan University children's Hospital anesthesia Department will provide the necessary treatment costs as well as appropriate financial compensation.

#### **6. Study on confidentiality of records**

We require each participating staff to sign confidentiality agreements, to ensure that our researchers do not give out your information. All research data is locked in a file cabinet, absolute confidentiality, only the project researchers have access to the information. Your examination and treatment information at scientific meetings or used in the literature, but not your personal information.

#### **7. Right to object**

You can volunteer to participate in this study, and withdraw from the study at any time without any consequences, participants in this study is without prejudice to any existing rights to your. You will receive a copy of the signed "informed notice" and "informed consent" copies. If you have any questions about this study, you can contact the project leader Wang Xuan, telephone number is 18017591058. You can also contact with Fudan University children's Hospital Research Ethics Board, telephone 021-64931913, which represents your interests.

# Informed consent

## 1. Informed consent or authorized signature

I have read or someone else has to read to me and understand the above information and content. All my questions have been satisfied with the answer. My participation in this research is voluntary,

I would like to participate in this study

Name: \_\_\_\_\_ Date \_\_\_\_\_

Guardian signature: \_\_\_\_\_ Date \_\_\_\_\_

\_\_\_\_\_

## 2. Investigators statement

I have already explained to the participants in this study and answer all the questions. I believe he is independently decided to participate in the study. I promise you, if the study found the drug's new use or others have found new adverse reaction, you will be informed in a timely manner.

Inspector signature: \_\_\_\_\_

Date : \_\_\_\_\_