

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of pilonidal sinus surgery complications between two methods of local and general anesthesia

#### Protocol summary

##### Summary

The aim of this randomized single-blind clinical trial is comparison of pilonidal sinus surgery complications between two methods of local and general anesthesia. A total of 60 patients, meeting eligibility criteria, will be randomly allocated into two equal groups. Local infiltration anesthesia group (n=30) received local anesthesia solution of 20ml:12ml lidocaine 2% , 1ml epinephrine 1/200000 , 6ml bupivacaine 0.5% , 50µg fentanyl (1ml); in sacrococcygeal region. General anesthesia for patients in the GA group will be used with intravenous midazolam 0.02ml/kg and fentanyl 3µg/kg as premedication and for induction from propofol 2mg/kg, atracurium 0.5 ml/kg. During surgery, anesthesia will be maintained on need by isoflurane MAC 1, 60% nitrous oxide, fentanyl, atracurium and at the end of anesthesia residual Neuromuscular blockade was antagonized with neostigmine 0.05 mg / kg and atropine 0.15 mg/kg. The amount of intraoperative bleeding duration of surgery, operation time and at the recovery in moments of 1, 10, 20 and 30 min respiratory rates, nausea and vomiting, o2 saturation and blood pressure will be recorded. A nurse ( a blinded observer) will assess post-operative pain at 3, 6, 24, 48 and 72 with a visual analogue scale after surgery. The amount and type of analgesic drugs prescribed and the duration of hospitalization after surgery will be recorded at questionnaire. Patients one week and one month after surgery will visit by surgen assistant (A Blinded observer) to assess wound infection, wound seroma and recurrence after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312031786N5**

Registration date: **2014-05-15, 1393/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-05-15, 1393/02/25

##### Registrant information

###### Name

Nasrin Rahmani

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1226 1700

###### Email address

nrahmani@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences

##### Expected recruitment start date

2013-03-21, 1392/01/01

##### Expected recruitment end date

2014-04-21, 1393/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of pilonidal sinus surgery complications between two methods of local and general anesthesia

##### Public title

Pilonidal sinus surgery under local anesthesia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: informed written consent; ASA class I-II.  
Exclusion criteria: recurrent and acute pilonidal sinus;  
substance abuse; cardiac disease; diabetes mellitus;  
sensitivity to local anesthetics; sever obesity (BMI>35).

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Mazandaran University of  
Medical Sciences

###### **Street address**

Mazandaran University of Medical Sciences, Moallem  
Square.

###### **City**

Sari

###### **Postal code**

4817844718

###### **Approval date**

2013-03-06, 1391/12/16

###### **Ethics committee reference number**

91-203

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Pilonidal sinus

##### **ICD-10 code**

L05.9

##### **ICD-10 code description**

Pilonidal cyst without abscess

### **Primary outcomes**

#### **1**

##### **Description**

The amount of intraoperative bleeding

##### **Timepoint**

At the end of operation

##### **Method of measurement**

Questionnaire

#### **2**

##### **Description**

The amount of intraoperative bleeding

##### **Timepoint**

At 3, 6, 24, 48 and 72 hours after surgery

##### **Method of measurement**

Visual Analog Scale

### **Secondary outcomes**

#### **1**

##### **Description**

O2 saturation

##### **Timepoint**

At the recovery in minutes 1, 10, 20 and 30

##### **Method of measurement**

Questionnaire

#### **2**

##### **Description**

Operation time

##### **Timepoint**

At the end of operation

##### **Method of measurement**

Questionnaire

#### **3**

##### **Description**

Respiratory rate

##### **Timepoint**

At the recovery in minutes 1, 10, 20 and 30

##### **Method of measurement**

Questionnaire

#### **4**

##### **Description**

Blood pressure

##### **Timepoint**

At the recovery in minutes 1, 10, 20 and 30

##### **Method of measurement**

Questionnaire

#### **5**

##### **Description**

The amount and type of analgesic drugs prescribed

##### **Timepoint**

During hospitalization  
**Method of measurement**  
Questionnaire

## 6

**Description**  
The duration of hospitalization  
**Timepoint**  
Hospitalization  
**Method of measurement**  
Questionnaire

## 7

**Description**  
Wound infection  
**Timepoint**  
One week and one month after surgery  
**Method of measurement**  
Questionnaire

## 8

**Description**  
Wound seroma  
**Timepoint**  
One week and one month after surgery  
**Method of measurement**  
Questionnaire

## 9

**Description**  
Recurrence  
**Timepoint**  
One week and one month after surgery  
**Method of measurement**  
Questionnaire

## **Intervention groups**

### 1

**Description**  
Local infiltration anesthesia group(Interventional)  
On=30)received local anesthesia solution of 20ml:12ml  
lidocaine 2% , 1ml epinephrine 1/200000 , 6ml  
bupivacaine 0.5% , 50µg fentanyl (1ml); in  
sacroccygeal region.  
**Category**  
Treatment - Drugs

### 2

**Description**  
General anesthesia for patients in the GA group(Control)  
will be used with intravenous midazolam 0.02ml/kg and  
fentanyl 3µg/kg as premedication and for induction from  
propofol 2mg/kg, atracurium 0.5 ml/kg.During surgery,  
anesthesia will be maintained on need by isoflurane MAC  
1, 60% nitrous oxide, fentanyl, atracurium and at the end  
of anesthesia residual Neuromuscular blockade was

antagonized with neostigmine 0.05 mg / kg and atropine  
0.15 mg/kg.

**Category**  
Treatment - Drugs

## **Recruitment centers**

### 1

**Recruitment center**  
**Name of recruitment center**  
Emam khomeni General Hospital  
**Full name of responsible person**  
Afshin Gholipour Baradari MD  
**Street address**  
Emam Khomeini Hospital, Amir mazandarani Ave.  
**City**  
Sari

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Vice chancellor for research, Mazandaran University  
of Medical Sciences  
**Full name of responsible person**  
Ahmad Ali Enayati MD  
**Street address**  
Mazandaran University of Medical Sciences, Moallem  
Square.  
**City**  
Sari  
**Grant name**  
10506  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Vice chancellor for research, Mazandaran University of  
Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## **Person responsible for general inquiries**

**Contact**  
**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Seyyed Mohamad Javad Heidari Yazdi

**Position**

Resident of Surgery

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**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Abolfazl Firouzian MD

**Position**

Anesthesiologist, Assistant Professor

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Nasrin Rahmani Boeni MD

**Position**

Surgen, Assistant Professor

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nrahmani@mazums.ac.ir drrahmani124@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*