

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

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Iran (Islamic Republic of)

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+98 15 1226 1700

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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 sacrococcygeal 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
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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

Other areas of specialty/work**Street address**

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

Mazandaran University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist, Assistant Professor

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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