Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, atracuriom 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

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Name of organization / entity
Mazandaran University of Medical Sciences
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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 sinos

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) 0n=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, atracuriom 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

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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