

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The evaluation of the effect of intrathecal fentanyl added to lidocain on shivering in women after abdominal hysterectomy

Protocol summary

Summary

The aim of this study is assessing the effect of added fentanyl to lidocain in the amount of shivering after abdominal hysterectomy in women. 70 women candidated for abdominal hysterectomy without histoy of allergy, cancer, obesity (body mass indexy 30kg/m2), contraindication to a spinal puncture will include in study and randomly divided into 2 groups.Group 1 will undergo spinal anesthesia using 75mg lidocain 5% and additional 30µg of fentanyl intrathecally. Group 2 will undergo spinal anesthesia using 75mg lidocain 5% and normal salin 0.6cc . The amount of of shivering three hours after spinal anesthesia will b measured according to crossly&mahajon Scale.Data will be assessed by chi-square test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022416162N2**

Registration date: **2015-04-20, 1394/01/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-20, 1394/01/31

Registrant information

Name

Masoomeh Nataj Majd

Name of organization / entity

Arash Womens Hospital, Tehran Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

hosparash@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of intrathecal fentanyl added to lidocain on shivering in women after abdominal hysterectomy

Public title

Effect of fentanyl and lidocain drugs in shivering after surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Patients condidate for abdominal hysterectomy Exclusion criteria: Patients with allergy, cancer, obesity (body mass indexy 30kg/m2), contraindication to a spinal puncture, patients on narcotics or sedatives

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Khlije Fars boulevard, Zahedan

City

Zahedan

Postal code**Approval date**

2015-02-08, 1393/11/19

Ethics committee reference number

124524-4 -93

Health conditions studied**1****Description of health condition studied**

shivering after surgery

ICD-10 code

R25.1

ICD-10 code description

Tremor, unspecified

Primary outcomes**1****Description**

shivering

Timepoint

3 hours after surgery

Method of measurement

observational

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group will undergo spinal anesthesia using 75mg lidocain 5% and additional 30µg of fentanyl intrathecally.

Category

Treatment - Drugs

2**Description**

Control Group will undergo spinal anesthesia using 75mg lidocain 5% and normal salin 0.6cc .

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali Ebne Abitleb Hospital

Full name of responsible person

Dr. Masoomeh Nataj Majd

Street address

Zahedan University of Medical Sciences, Dr. Hesabi square

City

Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor of Zahedan University of Medical Sciences

Full name of responsible person

Dr. Hooshang Rafighdoost

Street address

Zahedan University of Medical Sciences, Khalij Fars boulevard

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor of Zahedan 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

Zahedan University Of Medical Sciences

Full name of responsible person

Dr.Masoomeh Nataj Majd

Position

Anesthesiologist

Other areas of specialty/work

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Position

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

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