

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The clinical trial study of comparison intravenous pethidine and sterile water efficacy in prevention of shivering during cesarean section under spinal anesthesia

Protocol summary

Summary

In this double blind randomized clinical trial, 80 ASA I pregnant patients of 15-40 years old who have uncomplicated pregnancy and are candidates for cesarean section with spinal anesthesia will be selected. Patients with history of pethidine allergy; contraindication of pethidine injection; history of opioid addiction or opioid abuse and patient with severe shivering will be excluded. All participants after filling an informed consent will be randomly assigned into two groups: Group P (40 patients) will receive 20mg (2cc) pethidine and group C will receive 2cc of sterile water both intravenously. Heart rate, blood pressure, vomiting, nausea and blood oxygen will be recorded before anesthesia and each 5 minute after anesthesia. The Severity of shivering after spinal anesthesia will be compared between the groups. Patients will be controlled for side effects such as vomiting; nausea and hypotension before and after anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040527242N1**
Registration date: **2016-08-19, 1395/05/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-19, 1395/05/29

Registrant information

Name

Manizhe Yousefi moghadam

Name of organization / entity

Sabzevar university of medical sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial study of comparison intravenous pethidine and sterile water efficacy in prevention of shivering during cesarean section under spinal anesthesia

Public title

Pethidine efficacy in prevention of shivering during cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ISI I pregnant women 15-40 years old with normal pregnancy that candidate for cesarean section under spinal anesthesia Exclusion criteria: history of pethidine allergy; contraindication for pethidine

injection; history of opioid addiction or opioid abuse;
patient with sever shivering has been given drug

Age

From **15 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Sabzevar University of Medical Sciences

Street address

Central building of Sabzevar University of Medical
Science ,Asadabadi Street,Sabzevar

City

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Postal code

Approval date

2015-08-03, 1394/05/12

Ethics committee reference number

ir.medsab.rec.1394.64

Health conditions studied

1

Description of health condition studied

Effect of intravenous pethidine on preventing post spinal
anesthesia shivering in cesarean section

ICD-10 code

O89.4

ICD-10 code description

O89.4

Primary outcomes

1

Description

Shivering

Timepoint

Before spinal anesthesia; 5 min after spinal anesthesia;
every 10 min in operating room and recovery

Method of measurement

Grade 0 (no shivering) to grade 4 (involved whole body
muscles)

Secondary outcomes

1

Description

Nausea

Timepoint

After pethidine injection

Method of measurement

visual

Intervention groups

1

Description

Patient in Group P received 20mg (2cc) pethidine
intravenously before spinal anesthesia.

Category

Prevention

2

Description

Patient in Group C received 2cc strile water intravenously
before spinal anesthesia.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Shahidan Mobini Hospital

Full name of responsible person

Solmaz Dastres

Street address

Shahidan Mobini Hospital Kahefi street Sabzevar

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Manizheh Yousefi Moghadam
Street address
 Taleghani Street Sabzevar
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Sabzevar 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

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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