Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the incidence of post dural puncture headache following spinal anesthesia in sitting and lateral decubitous position in patients under caesarian section

Protocol summary

Summary

Objective: Comparing the incidence of post dural puncture headache following spinal anesthesia between the sitting and lateral decubitous positioned patients under caesarian section. Design: Single blinded randomized controlled trial setting. Setting and conduct: -Sitting positioned group: The patients legs are flattened opposite to the body. -Lateral positioned group: The patient is right lateral decubitus and her knees are fully flexed to the abdomen. The two groups: -will receive 300cc ringer lactate before the operation. -They will be anesthetised by injecting of 2 cc bupivacaine plus 1 cc sufentanyl by a NO: 24 needle midlinely through the l3-l4 space. -They will quickly be flattened upward after the procedure. Inclusion criteria; All elective cesarean candidates Exclusion criteria; Chronic and migraine headaches ; Any obstetrics complication ; Chronic use of analgesics ; Spinal anesthesia contraindications -Primary outcome: Headache, 24& 72 hours after the operation will be asked from the patients by a blinded person. Secondary outcomes: Anesthetic level: will be measured 5 minutes after anesthesia. Hypotension: The Blood pressure will be measured by non invasive blood pressure every 3 minutes, And will be treated by ephedrine, while noted. Nausea & vomiting: will be noted if were seen.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205059644N1**
Registration date: **2013-02-06, 1391/11/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-02-06, 1391/11/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2013-02-10, 1391/11/22

Expected recruitment end date

2013-03-12, 1391/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the incidence of post dural puncture headache following spinal anesthesia in sitting and lateral decubitous position in patients under caesarian section

Public title

The effect of sitting or lateral decubitous position on

postdural puncture Headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria; All elective cesarean candidates
Exclusion criteria; Chronic and migraine headaches ; Any obstetrics complication ; Chronic use of analgesics ; Spinal anesthesia contraindications

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

The ethic,s commity for the Hamedan university of medical sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamedan

Postal code

65178.518

Approval date

2011-12-17, 1390/09/26

Ethics committee reference number

3209/9/35/16/پ/د

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G97.0

ICD-10 code description

Cerebrospinal fluid leak from spinal puncture

Primary outcomes

1

Description

Headache

Timepoint

1st and 3th day after s/a

Method of measurement

pain scored ruler and the number of used analgesic

Secondary outcomes

1

Description

Nausea and Vomitting

Timepoint

Operation time, 1st and 3rd days after spinal anesthesia

Method of measurement

Question from the patients

2

Description

Sensory level

Timepoint

5 minutes after spinal anesthsia

Method of measurement

Stimulation by a needle

3

Description

Hypotension

Timepoint

Every 3 minutes

Method of measurement

Non invasive blood pressure

Intervention groups

1

Description

In the sitting positioned group the patient,s legs are flattend opposite to her face, then the procieduer will be done.

Category

N/A

2

Description

In the lateral postioned group, the patients will lye on right lateral position and keep their khnees flexed to their abdomen, then the prociedure will done.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
ندارد
Grant code / Reference number
000000
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research the Technology, Hamadan 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

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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