

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation the efficacy of intravenous propofol on post dural puncture headache incidence after cesarian section

Protocol summary

2016-04-29, 1395/02/10

Summary

The main objective: To determine the effect of intravenous propofol headache after spinal anesthesia for cesarean section. Study design: non-random. Inclusion criteria: pregnant women. Aged 18 -36. ASA class I, II. Exclusion criteria: history of headache. Housing consumption. opioid addiction . pulmonary/ heart disease. Diabetes. Other diseases that need treatment. Sample size: 120 women pregnant. After spinal anesthesia in left lateral position by Quincke spinal needle 25 in the first group after leaving baby propofol infuses dy pump at a rate of 30 micrograms per kilogram per minute for 30 minutes is injected through the green angiocut. The control group did not receive the drug in both groups headache severity in patients after surgery is measured by an anesthesiologist immediately after entering the recovery room and hours 1, 6, 12, 18, 24 after the discharge. The visual analogue scale of pain was measured. In case of headache patients with conventional treatment includes bed rest, hydration, use of analgesics, which includes acetaminophen codeine In this study, (300 mg acetaminophen and 20 mg codeine) administered every 6 hours using a corset. The patient is said to be visited until discharge from the hospital a week later with an anesthesiologist by a phone call if notify headache

Registrant information

Name

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Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603131616N5**

Registration date: **2016-04-29, 1395/02/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Scientific title

Evaluation the efficacy of intravenous propofol on post dural puncture headache incidence after cesarian section

Public title

Evaluation the efficacy of intravenous propofol on post dural puncture headache incidence after cesarian section

Purpose

Prevention

Inclusion/Exclusion criteria

Exclusion criteria: history of headache. Housing consumption. opioid addiction . pulmonary/ heart

disease. Diabetes. Other diseases that need treatment
Inclusion criteria: pregnant women. Aged 18 -36. ASA
class I, II.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kermanshah University of Medical Sciences Ethics
Committee

Street address

The central building , martyr Beheshti blvd.

City

Kermanshah

Postal code

6715847141

Approval date

2014-10-14, 1393/07/22

Ethics committee reference number

31546

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

Postdural Puncture Headache

ICD-10 code

G97.1

ICD-10 code description

Postdural Puncture Headache

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

Headache

Timepoint

1,6,18,24 hours and 2,3,4,5,6,7 days after spinal
anesthesia

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group: After spinal anesthesia by left latral
with Quincke spinal needle number 25 ,After leaving the
infant propofol infuses with a pump at a rate of 30
micrograms per kilogram per minute for 30 minutes is
injected through the IV green.The researcher must do
completely control of BP, PR, RR, ECG,consciousness .

Category

Prevention

2**Description**

In the control group no intervention was done The
researcher must do completely control of BP, PR, RR,
ECG,consciousness .

Category

Treatment - Drugs

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

Imam Reza Hospital

Full name of responsible person

Rasoul Mahdavi Jafari

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Sorkhe lijhe street

City

Kermanshah

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

Vice chancellor for research, Kermanshah University
of Medical Sciences

Full name of responsible person

Farid Najafi
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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
 Vice chancellor for research, Kermanshah 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
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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