Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

The evaluation effect of sufentanil and bupivacaine compared to bupivacaine alone in the prevention of post-spinal headaches caused by rupture of Dora layer in pregnant women undergoing caesarean section

Protocol summary

Summary

After the University Ethics Committeea approval in a randomized clinical trial 60 pregnant women candidate elective cesarean section with ASA class 1 or 2 included in the study and randomly in two groups of sufentanil with bupivacain and bupivacain alone. Patients with a history of coagulopathy, lack of consent to perform the spinal anesthesia, infection, history of anesthesia ,migraine headaches, seizures, severe preeclampsia, eclampsia, a history of low back pain and any mass in the CNS are excluded. Before induction of spinal anesthesia the objective of research and telecommunication follow up with patients were described as well as how to express the pain VAS by the criteria as well as to educate them. Before performing spinal anesthesia ,patiants consent were collected and in both groups 500 cc venous fluid were infused and bood pressure, pulse oximetry heart rate were monitored. In both groups, spinal anesthesia were in sitting position in L4-L5 space with spinal Quinke needle (25 G * 90mm). in one group 12.5 mg of bupivacain injected and in other group 12.5 mg of cell bupivacain with 5 µg sufentil were injected. in the check list information of patients and phone numbers for follow up added. And up to a week the phone call will performed . patients were admitted for three days and headache occurance were evaluted,and if any headache recorded the severity of the headaches in order to VAS added(VAS zero means completely without the headache and headache imaginable ten VAS is the strongest). In the case of mild and moderate headache patient support measures recommended in the event of a severe headache that disrupt the patians daily activities recomended to return to hospital and epidural blood patch were performed by the executive producer. Finally the information collected by the software Stata11 processed and the analysis of the case performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610162946N8**
Registration date: **2016-10-23, 1395/08/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-23, 1395/08/02

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6310

Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

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 evaluation effect of sufentanil and bupivacaine compared to bupivacaine alone in the prevention of post-spinal headaches caused by rupture of Dora layer in pregnant women undergoing caesarean section

Public title
The evaluation effect of sufentanil and bupivacaine compared to bupivacaine alone in the prevention of post-spinal headaches caused by rupture of Dora layer in pregnant women undergoing caesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
In this study, pregnant women 18 to 40 years undergoing elective cesarean section; ASA class I, II (American Society classification ofAnesthesia); BMI of 18.5 to 25 .patiants were entered to this study after giving informed consent. Patients with a history of bleeding disorder, lack of consent to perform spinal anesthesia, infection, migraine, history of seizures, severe preeclampsia, eclampsia, history of back pain and bulky mass in the CNS are excluded.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Kermanshah University of Medical Sciences

Street address
No. 2 building of Medical University, Shahid Beheshti boulevard

City
kermanshah

Postal code
6714415333

Approval date
2015-10-20, 1394/07/28

Ethics committee reference number
KUMS.REC.1394.497

Health conditions studied

1

Description of health condition studied
headache

ICD-10 code
g44.4

ICD-10 code description
Drug-induced headache, not elsewhere classified

Primary outcomes

1

Description
headache incidence and intencity

Timepoint
0 to 7 days after spinal anesthesia

Method of measurement
by visual analogue scale

Secondary outcomes

1

Description
vital sign changes

Timepoint
every 2 minute until 10minute then every 5 minute

Method of measurement
by datascope monitor

Intervention groups

1

Description
Spinal anesthesia is performed in sitting position between L4 - L5 spaces with spinal needle Quinke (25 G * 90mm) 12.5 mgbupivacaine with 5 mcg sufentanil used.

Category
Treatment - Drugs

2

Description
Spinal anesthesia is performed in sitting position between L4 - L5 spaces with spinal needle Quinke (25 G * 90mm) 12.5 mg bupivacaine used.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Mitra Yari
Street address
Parastar boulevard, Sorkhalijeh
City
kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for reasearch ,Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Imam Reza Hospital, Parastar boulevard, Sorkhalijeh
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kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for reasearch ,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
Kermanshah University of Medical Sciences
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assistant professor, anesthesiologist
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Person responsible for scientific inquiries

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Person responsible for updating data

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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