Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of intravenous dexamethasone and paracetamol in the prevention of post Dural puncture headache in elective cesarean section under spinal anesthesia

Protocol summary

Study aim

The comparison of intravenous dexamethasone and paracetamol in the prevention of post Dural puncture headache in elective cesarean section under spinal anesthesia

Design

Triple blind randomized clinical trial

Settings and conduct

Patients in the first group receive 8 mg dexamethasone in 100 cc normal saline while in the second group patients receive 1000 mg of paracetamol before the spinal anesthesia and patients in the third group received 100 ml of normal saline without preservatives before spinal anesthesia in the microsurgery via micro set and three way in 15 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA I-II Minimum NPO time = 8 hours, Elective cesarean section Exclusion criteria:Contraindications of Spinal anesthesia, Local infection in the lumbar region, Use anti-platelet and anticoagulant, Sensitivity to Local anesthesia, Diabetes mellitus,kidney Diseases, Renal failure, Coagulation disorder, Liver disease, Heart disease, History of seizure or any neurological disease, Migraine and pressure headaches. The history of drug addiction, Failure of spinal anesthesia or multiple attempts to perform spinal anesthesia more than once, Systolic blood pressure above 150 and less than 100, Preeclampsia,IUGR, Weight above 100 ,Height less than 150 and more than 180 cm , Hemoglobin less than 8, Cesarean section more than 3 times, Sensitivity to dexamethasone and paracetamol.

Intervention groups

patients in the first group receive 8 mg dexamethasone in 100 cc normal saline .Patients in the second group receive 1000 mg of paracetamol before the spinal anesthesia in 100 ml of normal saline .Patients in the third group received 100 ml of normal saline without preservatives before spinal anesthesia in the microsurgery via micro set and three way in 15 minutes.

Main outcome variables

Headache,Nausea and Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N80**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **prospective**

Last update: **2019-06-09, 1398/03/19**
Update count: **0**

Registration date

2019-06-09, 1398/03/19

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of intravenous dexamethasone and paracetamol in the prevention of post Dural puncture headache in elective cesarean section under spinal anesthesia

Public title

The comparison of intravenous dexamethasone and paracetamol in the prevention of post Dural puncture headache in elective cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I-II Minimum NPO time = 8 hours Elective cesarean section

Exclusion criteria:

Spinal anesthesia Contraindications of Local infection in the lumbar region (spinal cord needle entry site) Use anti-platelet and anticoagulant Sensitivity to Local anesthesia Diabetes mellitus kidney Diseases Renal failure Coagulation disorder Liver disease Heart disease History of seizure or any neurological disease Migraine and pressure headaches The history of drug addiction Failure of spinal anesthesia or multiple attempts to perform spinal anesthesia more than once Systolic blood pressure above 150 and less than 100 Preeclampsia IUGR The lack of proper growth of the uterus Weight above 100 Height less than 150 and more than 180 cm Hemoglobin less than 8 Caesarean section more than 3 times Sensitivity to dexamethasone and paracetamol

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **290**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to one of two groups using the www.Randomizer.org website.

Blinding (investigator's opinion)

Double blinded

Blinding description

All drug solutions of this study will be prepared by the only person who is aware of the study group in similar syringes of the same size and shape and will be provided to anesthetist for injection.Anesthesiologist, patients, and other collaborating staff will be unaware of the design of each patient's study group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand streetخیابان

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.130

Health conditions studied

1

Description of health condition studied

cesarean

ICD-10 code

P03.4

ICD-10 code description

Newborn (suspected to be) affected by Cesarean delivery

Primary outcomes

1

Description

Headache

Timepoint

At the arrival to the recovery room and after discharge from the recovery room at 6,12,24,48,72 hr.

Method of measurement

Visual Analog Score

Secondary outcomes

1

Description
Incidence of Nausea and Vomiting
Timepoint
At the arrival to the recovery room and after discharge from the recovery room at 6,12,24,48,72 hr.
Method of measurement
Observasion

Intervention groups

1

Description
Interventional group: patients in the first group receive 8 mg dexamethasone in 100 cc normal saline via micro set and three way in 15 minutes.
Category
Prevention

2

Description
Intervention group:Patients in the second group receive 1000 mg of paracetamol before the spinal anesthesia in 100 ml of normal saline via micro set and three way in 15 minutes.
Category
Prevention

3

Description
Control group: Patients in the third group received 100 ml of normal saline without preservatives before spinal anesthesia in the microsurgery via micro set and three way in 15 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Mohammad Hosein Pourjafarian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand
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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hosein Pourjafarian
Position
Anesthesiology Resident
Latest degree
Medical doctor
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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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available