Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of intravenous fluid therapy before spinal block on postural headache in women undergoing elective cesarean section

Protocol summary

Study aim
The purpose of this study was to evaluate the role of intravenous fluid therapy in the waiting room before entering the operating room on the incidence, severity and duration of postdural puncture headache.

Design
A randomized, single-blind, intervention-controlled clinical trial.

Settings and conduct
This study is a single-blind clinical trial in women undergoing elective cesarean section referring to the NickNafs training centers and the gynecology ward of Ali Ibn Abi Talib Hospital, rafsanjan, Iran.

Participants/Inclusion and exclusion criteria
Main inclusion: 1. Pregnant mothers who are candidates for elective cesarean section. 2. Usually fast for 8 hours or more. Main exclusion: 1. Women who suffer from lumbar lordosis, high weight and lack of coordination, numbness in the first instance, or partial numbness, and have to take analgesics and sleep medications to continue. 2. Women who have a history of migraine or tension or headache due to high blood pressure.

Intervention groups
Intervention was performed, each containing 75 candidates for elective cesarean section. After a minimum fasting period, women received 500 cc of Ringer serum one hour before the start of the spinal block. The incidence, severity and duration of their headache were evaluated. In the control group, women were admitted to the operating room with a minimum of eight hours of fasting in the morning and received no serum.

Main outcome variables
Postural headache (or incidence of postural headache) in both groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190817044544N1**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **retrospective**

Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date
2020-01-03, 1398/10/13

Registrant information

Name
Fatemeh Jadidi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3428 0185

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dr.fjadidi@rums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-09, 1397/01/20

Expected recruitment end date
2019-08-11, 1398/05/20

Actual recruitment start date
2018-04-09, 1397/01/20

Actual recruitment end date
2019-08-19, 1398/05/28

Trial completion date
2019-08-19, 1398/05/28

Scientific title
Effect of intravenous fluid therapy before spinal block on postural headache in women undergoing elective cesarean section

Public title
Effect of intravenous fluid therapy before spinal block on postural headache in women undergoing elective cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant mothers who are candidates for elective cesarean section. usually fast for 8 hours or more.
Exclusion criteria:
Women who suffer from lumbar lordosis, high weight and lack of coordination, numbness in the first instance, or partial numbness, and have to take analgesics and sleep medications to continue. Women who have a history of migraine or tension or headache due to high blood pressure.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator

Sample size
Target sample size: **150**
Actual sample size reached: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in this study were divided into control and intervention groups using simple randomization (random number tables).
Blinding (investigator's opinion)
Single blinded
Blinding description
The population of the study was two groups of women. One group received 500 cc Ringer serum before entering the operating room and the other group did not receive this serum. Patients in our study were aware of serum intake but were unaware of the purpose of serum therapy.
Placebo
Not used
Assignment
Parallel
Other design features
In women undergoing elective cesarean section, postural puncture headache indices were compared between the two groups for the effect of fluid therapy before spinal anesthesia.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of rafsanjan University of Medical Sciences
Street address
Rafsanjan, Imam Ali Boulevard
City
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Kerman
Postal code
7717933777
Approval date
2018-08-08, 1397/05/17
Ethics committee reference number
IR.RUMS.REC.1397.095

Health conditions studied

1

Description of health condition studied
Postdural puncture headache
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
incidence of headache
Timepoint
Women in the two groups were visited for seven days after the intervention for headache
Method of measurement
The specific measurement tool for measuring primary outcome (incidence of headache) is based on a researcher-made checklist.

Secondary outcomes

1

Description
1-headache severity, 2- day of onset of headache, 3- number of day headaches, 4- frequency need of analgesic, 5-frequency of use.
Timepoint
In case of a headache, women are screened daily for other relevant indicators within seven days after delivery.
Method of measurement
The specific measurement tool for the severity of headache has been the use of the VAS (Visual Analogue Scale) ruler.

Intervention groups

1

Description
Intervention group: each containing 75 candidates for elective cesarean section. After a minimum fasting period, women received 500 cc of Ringer serum one hour before the start of the spinal block. The incidence, severity and duration of their headache were evaluated.
Category
Rehabilitation

2

Description
Control group: women were admitted to the operating room with a minimum of eight hours of fasting in the morning and received no serum.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Rafsanjan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
None
Grant code / Reference number
none
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
None
Proportion provided by this source
1
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
Rafsanjan University of Medical Sciences
Full name of responsible person
fatemeh Jadidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available