

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)

Phone

+98 34 3428 0185

Email address

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

rafsanjan

Province

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

Fatemeh Jadidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

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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

Anesthesiology

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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