

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of early and immediate oral hydration on post-cesarean section outcome

Protocol summary

Study aim

Comparison of early and immediate oral hydration on post-cesarean section outcome

Design

This single-blind randomized clinical trial with parallel groups (Third phase) will be performed on 26 women undergoing cesarean section with spinal anesthesia. In this study, block randomization method will be used. Random allocation software is also used to generate a random sequence of blocks. In the intervention group, oral fluid therapy for patients will begin during the first two hours after surgery. In the control group, oral feeding will be started within six hours after surgery.

Settings and conduct

This single-blind randomized clinical trial study with parallel groups will be performed on 26 women undergoing cesarean section with spinal anesthesia in Zanjan academic hospital. In this study, data collectors, outcome assessors, and manuscript writers will be completely unaware of the drug prescribing protocol. In the intervention group, oral fluid therapy for patients will begin during the first two hours after surgery. In the control group, oral feeding will be started within six hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria include pregnant women undergoing cesarean section under spinal anesthesia. Patients with a history of HTN, heart disease, body mass index more than 30 and people with preeclampsia will be excluded.

Intervention groups

In the intervention group, oral fluid therapy for patients will begin during the first two hours after surgery.

Main outcome variables

hospital stay length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220517054893N1**

Registration date: **2022-05-25, 1401/03/04**

Registration timing: **prospective**

Last update: **2022-05-25, 1401/03/04**

Update count: **0**

Registration date

2022-05-25, 1401/03/04

Registrant information

Name

Aida Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3335 3053

Email address

aida.rezaei@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-02, 1401/04/11

Expected recruitment end date

2023-01-01, 1401/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early and immediate oral hydration on post-cesarean section outcome

Public title

Comparison of early and immediate oral hydration on post-caesarean section outcome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women undergoing cesarean section by spinal anesthesia

Exclusion criteria:

Hypertention Body mass index more than 30
Preeclampsia Heart disease

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. The size of all blocks is equal. Random allocation software is also used to generate a random sequence of blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data collectors, outcome assessors, and manuscript writers will be completely unaware of the prescribing protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhori BLV.
Azadi Squ. Zanjan

City

zanjan

Province

Zanjan

Postal code

1435689752

Approval date

2022-05-10, 1401/02/20

Ethics committee reference number

IR.ZUMS.REC.1401.052

Health conditions studied

1

Description of health condition studied

Hospital stay length

ICD-10 code

O75.82

ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

Primary outcomes

1

Description

Hospital stay length

Timepoint

Days of hospitalization after surgery

Method of measurement

Based on day

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, oral fluid therapy for patients will begin during the first two hours after surgery.

Category

Treatment - Drugs

2

Description

Control group: In the control group, oral fluid therapy for patients will begin during the six hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person
Aida Rezaei
Street address
Ayatollah Mousavi Hospital, Gavazang Road, Zanjan
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1425678922
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+98 21 8806 4148
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aida.rezaei@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Samad Nadri
Street address
Zanjan University of Medical Sciences Campus, Dr.
Yousef Sabouti Blvd., Zanjan
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4513956184
Phone
+98 24 3301 8100
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riasat@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person

Aida Rezaei
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long

Access period starts from 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable

Contact Dr. Aida Rezaei (aida.rezaei@zums.ac.ir) at Zanjan University to receive the required documents or data.

What processes are involved for a request to access data/document

To submit a request, it is enough to contact the mentioned expert and send a written and signed request to her.

Comments