Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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-cesarean 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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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
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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

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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