Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of early oral feeding on consequences and complications of elective Cesarean section

Protocol summary

Study aim

To determine the effect of early initiation of oral feeding on the time to first bowel movement in the population of patients undergoing elective cesarean section. To determine the effect of early initiation of oral feeding on the time to first flatus passage in the population of patients undergoing elective cesarean section. To determine the effect of early initiation of oral feeding on gastrointestinal complications in the population of patients undergoing elective cesarean section.

Design

This was a phase 2, randomized, parallel-group, single-blind, controlled clinical trial conducted on 120 patients. Randomization was performed using the rand function in Excel software.

Settings and conduct

All patients undergo elective cesarean section in the morning. Initiation of feeding at the specified time points: In the first group, 4 hours after surgery, patients receive warm tea followed by hospital diet. In the second group, 8 hours after surgery, patients receive warm tea followed by hospital diet. Patients are provided with a questionnaire to record the time of first flatus passage and bowel movement. Nurses assess and record gastrointestinal symptoms such as nausea, vomiting, and anorexia using a checklist.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women at or beyond 37 weeks of gestation who are candidates for elective cesarean section under spinal anesthesia. Exclusion Criteria: Women who experienced postoperative hemorrhage or any other complication.

Intervention groups

1-Patients who experience early oral feeding 4 hours after cesarean delivery (Intervention group) 2-Patients who receive oral feeding 8 hours after cesarean delivery (Control group)

Main outcome variables

To determine the effect of early initiation of oral feeding on postoperative outcomes and complications in patients undergoing elective cesarean section.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240630062285N1**
Registration date: **2024-07-05, 1403/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-05, 1403/04/15**
Update count: **0**

Registration date

2024-07-05, 1403/04/15

Registrant information

Name

Arian Faramarzinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5565 8500

Email address

ma-dohadi@tums.student.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-01, 1403/04/11

Expected recruitment end date

2024-09-18, 1403/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of early oral feeding on consequences and complications of elective Cesarean section

Public title
Effect of early oral feeding on consequences of Cesarean section

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women at or beyond 37 weeks of gestation who are candidates for elective cesarean section under spinal anesthesia

Exclusion criteria:
Patients who experienced severe adhesions during their cesarean section Procedure duration was longer than 45 minutes Women with underlying gastrointestinal conditions such as inflammatory bowel disease Patients with emergency delivery indications (e.g., placenta previa, premature rupture of membranes, etc.) Patients who, for any reason, including contraindications to general anesthesia or spinal anesthesia, or personal preference, did not receive spinal anesthesia during their cesarean section Women who experienced postoperative hemorrhage

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants were randomly assigned to groups using a computer-generated random number sequence with a block size of four. The generated identifiers were placed in sealed envelopes by a statistician and attached to the doctor's order sheets. The envelopes were opened after surgery, and the information was manually recorded onto the clinicians' order sheets. Nurses provided oral feedings to the participants. The analyzer was blinded to the group assignments, but the participants and nurses were not.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants were randomly assigned to groups using a computer-generated random number sequence with a block size of four. The generated identifiers were placed in sealed envelopes by a statistician and attached to the doctor's order sheets. The envelopes were opened after surgery, and the information was manually recorded onto the clinicians' order sheets. Nurses provided oral feedings to the participants. The analyzer was blinded to the group assignments, but the participants and nurses were not. The same person who distributed the informed consent and performed the analysis was the blinded assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Baharloo hospital, Behdari street., Rahahan square.

City
Tehran

Province
Tehran

Postal code
1594654813

Approval date
2023-02-07, 1401/11/18

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.743

Health conditions studied

1

Description of health condition studied
post operative ileus

ICD-10 code
K56.7

ICD-10 code description
Ileus, unspecified

Primary outcomes

1

Description
Time to pass flatus post cesarean

Timepoint
Every 6 hours until the patient experiences first flatus passage.

Method of measurement
Patient self-report and documentation in the medical record.

Secondary outcomes

1

Description
Time to first bowel movement after cesarean section
Timepoint
Every 6 hours until the patient experiences first bowel movement
Method of measurement
Patient self-report and documentation in the medical record

2

Description
Maternal satisfaction with hospital stay
Timepoint
At the end of hospitalization
Method of measurement
Visual Analogue Scale

3

Description
abdominal cramp
Timepoint
Every 6 hours throughout the hospital stay.
Method of measurement
Patient self-report and physician examination using a checklist.

Intervention groups

1

Description
Intervention group: Patients who experience early oral feeding 4 hours after cesarean delivery. Patients undergo elective cesarean section in the morning. Initiation of feeding 4 hours after surgery with warm tea followed by hospital diet. Patients are advised to avoid raw fruits, milk, and legumes for 12 hours after the operation.
Category
Treatment - Other

2

Description
Control group: Patients who experience early oral feeding 8 hours after cesarean delivery. Patients undergo elective cesarean section in the morning. Initiation of feeding 8 hours after surgery with warm tea followed by hospital diet. Patients are advised to avoid raw fruits, milk, and legumes for 12 hours after the operation.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Baharloo Hospital
Full name of responsible person
Zahra Ghaleh Noy
Street address
Baharloo Hospital., Behdari Street., Rahahan Square
City
Tehran
Province
Tehran
Postal code
1594654813
Phone
+98 21 5565 8500
Email
baharloo@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice President for Research and Technology at the University
Street address
The northern wing of Tehran University., 16 Azar Street., Enghelab Square
City
Tehran
Province
Tehran
Postal code
141556619
Phone
+98 21 8898 9120
Email
Ma-dohadi@tums.student.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Arian Faramarzinia

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Baharloo hospital, Behdari street, Rahahan square

City
Tehran

Province
Tehran

Postal code
1594654813

Phone
+98 21 5565 8500

Fax

Email
Arianfaramarzinia79@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Arian Faramarzinia

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
Gynecology and Obstetrics

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Phone
+98 21 5565 8500

Email
Arianfaramarzinia79@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Arian Faramarzinia

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1594654813

Phone
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Fax

Email
Arianfaramarzinia79@gmail.com

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
Undecided - It is not yet known if there will be 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
No - There is not 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
After completing the study, the results of the study will be published in the form of a scientific article, and the data will be accessible through correspondence with the corresponding author.

When the data will become available and for how long
The possibility of accessing the data will be available after the publication of the study results in scientific journals, which will be around 9 months after the completion of the study.

To whom data/document is available
The data will be made available to researchers and decision-makers in the healthcare system.

Under which criteria data/document could be used
The data will be made available if the purpose of the research is to improve healthcare for patients, while maintaining the privacy of the participants.

From where data/document is obtainable
Contact the corresponding author

What processes are involved for a request to access data/document
The process of accessing the data is through correspondence by email or telephone contact with the corresponding author.

Comments