

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effects of early mouth feeding on the amount of pain in elective cesarean patients

Protocol summary

Study aim

The effects of early feeding on the amount of pain in elective cesarean patients, admitted to Imam Khomaii hospital In Divandareh 1395

Design

This study will be performed on 126 patients under elective cesarean section having the qualification of entering this study, they will be divided into intervention and control groups. The pain will be measured based on the VAS instrument and recorded as the time of entering the department, 6,12,18, and 24 hours after surgery.

Settings and conduct

People studied in this research will include all Cesarean section patients admitted to the women ward in Imam Khomeini Hospital of Divandareh. After obtaining the consent of the university Ethics Committee and receiving an introduction letter from the university research assistant and getting the permission from the hospital and gynecology department of the Imam Khomeini Hospital, the researcher will attend at the morning shift of the hospital delivery department. She will study the Pregnant elective cesarean women files and will select the qualified ones. Then, the goals of the survey will be explained to the qualified patients and informed consent will be taken from them and data collection will begin. Sampling will be available and after selecting the samples randomly using closed envelopes, they will be in one of the two groups: control or start feeding early with the liquid diet.

Participants/Inclusion and exclusion criteria

Entry criteria includes singleton pregnant women, 38-42 weeks of pregnancy, elective Cesarean (history of at least another previous cesarean). Exit criteria: Needing for blood transfusion for any cause, postoperative fever, post-partum anomalies diagnosis.

Intervention groups

Patients in the intervention group (early feeding with liquid diet) will be placed in sitting position 6 hours after surgery. Mouth feeding, Initially, 30 ml equals to half of a

glass of tea and 4 cubes of dissolved sugar will be given to the mother. Then, in case of tolerance and lack of nausea and vomiting after an hour, this volume doubles and can drink 60 ml of the liquid. After this time, based on the dietary intake of the patients, patients will receive juice and yogurt in the form of a soup diet if they tolerate and do not have nausea and vomiting, so that the patient's minimum fluid intake will be 1500 ml for each person per 24 hours. After starting mouth feeding, the flow of the vein fluid will be stopped. Before starting feeding, the pain of the mothers will be measured and recorded. The amount of pain at the time of entering the department, 24,18,12,6 after surgery, is determined by the pain reliever and will be recorded by the researcher in the questionnaire. Patients in the control group will be treated according to the routine care. Meaning they will lie down on the back position for 12 hours without eating or drinking anything. The amount of pain at the time of entering the department, 24,18,12,6 after surgery, is determined by the pain reliever and will be recorded by the researcher in the questionnaire.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170110031865N3**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Zahra Rashidei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-07-26, 1397/05/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of early mouth feeding on the amount of pain in elective cesarean patients

Public title

The Effect of early mouth feeding on the post-cesarean pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

women with singleton pregnancies gestational age 38 to 42 weeks elective cesarean (History: at least another previous Cesarean) surgery with a cross-section of the abdomen and spinal anesthesia vital signs within normal non-smoker and no addiction to drugs lack of any history of abdominal surgery other than caesarean Child alive Willing to participate in the study

Exclusion criteria:

patients giving up for any reason medical disorders and Midwifery (diabetes , anemia, high blood pressure, heart disease, cardiovascular, renal, pulmonary, gastrointestinal, thyroid, immune disorders, infectious, psychiatric, metabolic disorders, electrolyte and irritable bowel syndrome)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 126

Randomization (investigator's opinion)

Randomized

Randomization description

When entering the department, research units will be placed in one of the control or intervention groups (early liquids) using a simple random method using closed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The sample patients will be chosen by using closed envelopes randomly, and they will be placed in either groups (control or intervention with early liquid diet).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Pasdaran street, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Approval date

2017-02-22, 1395/12/04

Ethics committee reference number

IR.MUK.REC.1395/354

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

N94

ICD-10 code description

Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description

Pain

Timepoint

Arrival, 6,12,18 and 24 hours after surgery.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Patients in the intervention group (early feeding with liquid diet) will be placed in sitting position 6 hours after surgery. Mouth feeding, Initially, 30 ml equals to half of a glass of tea and 4 cubes of dissolved sugar will be given to the mother. Then, in case of tolerance and lack of nausea and vomiting after an hour, this volume doubles and can drink 60 ml of the liquid. After this time, based on the dietary intake of the patients, patients will receive juice and yogurt in the form of a soup diet if they tolerate and do not have nausea and vomiting, so that the patient's minimum fluid intake will be 1500 ml for each person per 24 hours. (If the nausea and vomiting of the patient are in an extent that they are not eager to eat and the fluids are less than 200 ml in 4 hours, the infusion of fluids continues and the person leaves the study). After starting mouth feeding, the flow of the vein fluid will be stopped. Before starting feeding, the pain of the mothers will be measured and recorded. The amount of pain at the time of entering the department, 24,18,12,6 after surgery, is determined by the pain reliever and will be recorded by the researcher in the questionnaire.

Category

Other

2

Description

Control group: Patients in the control group will be treated according to the routine care. Meaning they will lie down on the back position for 12 hours without eating or drinking anything. The amount of pain at the time of entering the department, 24,18,12,6 after surgery, is determined by the pain reliever and will be recorded by the researcher in the questionnaire.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Rashidei

Street address

Imam Khomeini street

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Divvandareh

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Kurdistan

Postal code

6641967397

Email

zrashidei@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research and technology of Kurdistan University of Medical Sciences

Full name of responsible person

Farzin Rezaee

Street address

Vice Chancellor for research and technology of Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research and technology of Kurdistan 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

2

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ronak Shahoei

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Imam khomainsi street.Imam khomainsi hospital

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sanandaj 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**

Kurdistan University of medical sciences

Full name of responsible person

zahra rashidei

Position

Nurse/MS.C

Latest degree

Bachelor

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Latest degree

Ph.D.

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Kurdistan University of Medical Sciences

Full name of responsible person

Ronak Shahoei

Position

ph.D/Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

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Web page address**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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main consequence of the study is shared.

When the data will become available and for how long
Six months after the publication of the article
To whom data/document is available
Researchers working in academic and academic institutions
Under which criteria data/document could be used
Use results in related studies
From where data/document is obtainable
E-mail address, contact number
What processes are involved for a request to access data/document
A maximum of one month from the first e-mail
Comments