Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Khomaini 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)

Phone
+98 918 773 1082

Email address
zrashidei@muk.ac.ir

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 Analoge 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

City

Divvandareh

Province

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

City

sanandaj

Province

Kurdistan

Postal code

6641967397

Phone

+98 87 3872 0241

Email

zrashidei@yahoo.com

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

Street address
Imam khomaini street.Imam khomaini hospital
City
Divvandareh
Province
Kurdistan
Postal code
6641967397
Phone
+98 87 3872 0241
Fax
+98 87 3872 0241
Email
zrashidei@yahoo.com

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
Other areas of specialty/work
Street address
Imam khomaini street
City
Divvandareh
Province
Kurdistan
Postal code
6641967397
Phone
+98 87 3872 2930
Fax
Email
zrashidei@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University of medical sciences
Full name of responsible person
Ronak Shahoei
Position
Assistant professor.Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Street address
Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Phone
+98 87317464
Fax
Email
zrashidei@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
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
Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj
City
Sanandaj
Province
Kurdistan
Postal code
66177 -13446
Phone
+98 87
Fax
Email
zrashidei@yahoo.com
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