

# 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)

**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 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

#### 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

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##### Province

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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

**Street address**

Imam khomainsi street.Imam khomainsi hospital

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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**

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**Full name of responsible person**

Ronak Shahoei

**Position**

Assistant professor.Ph.D

**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**

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

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**Province**

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**Postal code**

66177 -13446

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**Fax****Email**

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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**