

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of preoperative oral carbohydrate before cesarean section on breastfeeding

#### Protocol summary

##### Summary

The purpose of the study: Evaluation of effectiveness of oral preoperative carbohydrate on breastfeeding in the first 36 hours after cesarean section . Study design: Randomized, double-blind, placebo-controlled, single-center Phase 2-3 trial. Method: pregnant women scheduled for elective cesarean section with regional anesthesia ( spinal ) , age 20-35 years, gestational age  $\geq 38$  weeks, body mass index 25-37, after signing the informed consent divided randomly into two groups ( intervention=45 N, control=45 N ) . Exclusion criteria: history of gastrointestinal disorders , Diabetes Mellitus, gastrointestinal surgery ( stomach and intestinal ) , liver , kidney and cardiovascular disorders; history of complications related to this pregnancy ( preeclampsia, high-risk pregnancy, gestational diabetes mellitus ); Use of general anesthesia; Intraoperative blood loss of more than 1000 ml; Bowel and bladder injury during surgery; The use of dextrose during surgery; Failure to follow the instructions use of supplement; Any problems occur for the baby that mother is unable to breastfeeding; If surgery is longer than 45 minutes; Unwillingness person to continue cooperation. Patients in the intervention group ingested 800 ml of oral carbohydrate (12.5 per cent carbohydrates , 50 kcal/100 ml , 290 mOsm/kg) and control group 800 ml of flavoured water ( 0kcal/100ml ) in the day before operation between 8 and 24 hours . All persons were allowed to eat and drink freely before midnight . After midnight , persons were allowed no oral intake , except for 400 ml of the beverage ( oral carbohydrate for intervention and flavoured water for control group ) at 2 h before the initiation of anesthesia . The first time breastfeeding , the number of breastfeeding and the average duration of breastfeeding check and compare by questionnaire in the first 36 hours after surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016072629082N1**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-31, 1395/06/10

##### Registrant information

##### Name

Razieh Khalooei Fard

##### Name of organization / entity

Tehran University of Medical Sciences Department of Nutrition and Dietetic

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8895 5975

##### Email address

rkhaloofard@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research , International Campus  
Tehran University of Medical Sciences

##### Expected recruitment start date

2016-05-31, 1395/03/11

##### Expected recruitment end date

2016-08-21, 1395/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of preoperative oral carbohydrate before cesarean section on breastfeeding

### Public title

The effect of carbohydrate on breast feeding

### Purpose

Other

### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women scheduled for elective cesarean section with regional anesthesia ( spinal ) , age 20-35 years, gestational age  $\geq$ 38 weeks, body mass index 25-37 Exclusion criteria: history of gastrointestinal disorders , Diabetes Mellitus, gastrointestinal surgery ( stomach and intestinal ) , liver , kidney and cardiovascular disorders; history of complications related to this pregnancy ( preeclampsia, high-risk pregnancy, gestational diabetes mellitus ); Use of general anesthesia; Intraoperative blood loss of more than 1000 ml; Bowel and bladder injury during surgery; The use of dextrose during surgery; Failure to follow the instructions use of supplement; Any problems occur for the baby that mother is unable to breastfeeding; If surgery is longer than 45 minutes; Unwillingness person to continue cooperation

### Age

From **20 years** old to **35 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Room 605, Sixth floor, Central building of Tehran University of Medical Sciences, Quds Street intersection and Keshavarz Blvd, Tehran

##### City

Tehran

##### Postal code

##### Approval date

2016-05-28, 1395/03/08

##### Ethics committee reference number

IR.TUMS.REC.1395.2636

## Health conditions studied

### 1

#### Description of health condition studied

cesarean section

#### ICD-10 code

O82.9

#### ICD-10 code description

Delivery by caesarean section, unspecified

## Primary outcomes

### 1

#### Description

The first time breastfeeding after surgery

#### Timepoint

After intervention, after surgery

#### Method of measurement

questionnaire

### 2

#### Description

The number of breastfeeding

#### Timepoint

After intervention, in the first 36 hours after surgery

#### Method of measurement

questionnaire

### 3

#### Description

The average duration of breastfeeding ( minute)

#### Timepoint

After intervention, in the first 36 hours after surgery

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group : persons ingested 800 ml of the oral carbohydrate (12.5 per cent carbohydrates , 50 kcal/100 ml , 290 mOsm/kg) the day before operation between 8 and 24 hours. there were no food or drink restriction before midnight. After midnight , persons were allowed no oral intake except another 400 ml of the same beverage 2 h before the initiation of anesthesia .

### Category

Placebo

2

### Description

Control group : persons ingested 800 ml of the oral carbohydrate (0kcal/100ml) the day before operation between 8 and 24 hours. there were no food or drink restriction before midnight. After midnight , persons were allowed no oral intake except another 400 ml of the same beverage 2 h before the initiation of anesthesia .

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shabihkhani Hospital of Kashan

#### Full name of responsible person

Zohre Tabasi ( Gynecologist and Obstetrics , Associate Professor)

#### Street address

Martyr Beheshti Avenue, Kashan

#### City

Kashan

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research , International Campus  
Tehran University of Medical Sciences

#### Full name of responsible person

Vice chancellor for research

#### Street address

No. 124, Third Floor, International Campus, North M  
Street martyr brothers, Vali Asr Ave, Tehran

#### City

Tehran

#### 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 , International Campus  
Tehran University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

School of Nutritional Sciences & Dietetics, Tehran  
University of Medical Sciences

#### Full name of responsible person

Razieh Khalooei Fard

#### Position

Student of master in Nutrition and Dietetic

#### Other areas of specialty/work

#### Street address

No: 44, Hojjat-dost Alley, Naderi Street, Keshavarz  
Blvd, Tehran

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shkhalooei1367@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of Nutritional Sciences & Dietetics, Tehran  
University of Medical Sciences

#### Full name of responsible person

Saeed Hosseini

#### Position

Nutritionist and Dietitian, Associate Professor

#### Other areas of specialty/work

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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

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**City**

Tehran

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*