Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ≥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 , Diebetes Mellitus, gastrointestinal surgery (stomach and intestinal) , liver , kidney and cardiovascular disorders; history of complications related to this pregnancy (preeclapsia, 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 , exceot 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

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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 ≥38 weeks, body mass index 25-37 Exclusion criteria: history of gastrointestinal disorders , Diebetes Mellitus, gastrointestinal surgery (stomach and intestinal) , liver , kidney and cardiovascular disorders; history of complications related to this pregnancy (preeclapsia, 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

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Person responsible for scientific inquiries

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Position
Nutritionist and Dietitian, Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work
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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