

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of early-start nutrition (after 2hr) versus delayed-start nutrition (after 8hr) on gastrointestinal complications and patients satisfaction after cesarean surgery

Protocol summary

Summary

Two hundred pregnant women who undergo Cesarean section will be recruited and divided in two groups. This study and its probable complications will be explained for all eligible women and informed consent will be taken. Type of anesthesia in 2 groups is the same (Both are spinal anesthesia). In early-start nutrition group, liquids will be begun after 2 hours, and if they tolerate, semi-solid & solid diet will be continued. In delayed-start nutrition group, liquid will be started 8 hours after operation and if they tolerate, semi-solid & solid diet will be continued. Finally, incidence of vomiting, time of intestinal sound establishment (hr), time of gas ejection (hr), time of stool ejection, beginning of normal diet (hr), duration of admission to discharge and also patient satisfaction will be determined by themselves in both groups. The points that we should note in questionnaire consist of: demographic data such as age, BMI, pregnancy age, type of section (transverse or vertical), duration of operation, adhesion amount and urinary output.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138712211760N1**
Registration date: **2009-09-09, 1388/06/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-09-09, 1388/06/18

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 2282

Email address

zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of early-start nutrition (after 2hr) versus delayed-start nutrition (after 8hr) on gastrointestinal complications and patients satisfaction after cesarean surgery

Public title

Effect of early-start nutrition (after 2hr) versus delayed-start nutrition (after 8hr) on gastrointestinal complications and patients satisfaction after cesarean surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women that will undergo Cesarean section and aged 18-40 yr. Exclusion criteria: history of gastrointestinal disease such as: intestine occlusion, stomach surgery, intestinal surgery, adhesion and intestinal manipulation repair; Obstetrics complications such as: pregnancy fat liver, placenta abruption, chorioamnionitis, preeclampsia; surgery complications such as: severe hemorrhage.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Gangafroz Avenue

City

Babol

Postal code

4717641367

Approval date

2008-03-08, 1386/12/18

Ethics committee reference number

RV/11

Health conditions studied

1

Description of health condition studied

Cesarean section surgery complication

ICD-10 code

O94

ICD-10 code description

Sequelae of complication of pregnancy, childbirth and the puerperium

2

Description of health condition studied

Nutrition after Cesarean section

ICD-10 code

O99

ICD-10 code description

Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

borborygmi time

Timepoint

the hours after the nutrition

Method of measurement

physical exam

2

Description

vomiting, gas passing time, defecation time, time of start of normal diet

Timepoint

the hours after the nutrition

Method of measurement

question

3

Description

Patient satisfaction

Timepoint

release time

Method of measurement

visual analog scale [from zero (nonsatisfaction) to 100 (full satisfaction)]

4

Description

duration of admission

Timepoint

release time

Method of measurement

hours

Secondary outcomes

1

Description

urinary output

Timepoint

from nutrition time up to 24 hr (every 4 hr)

Method of measurement

millilitre

Intervention groups**1****Description**

delayed-start nutrition (after 8hr) as control group

Category

Other

2**Description**

early-start nutrition (after 2hr) as intervention group

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Yahyanejad Hospital

Full name of responsible person

Dr. seddigheh esmaeilzadeh

Street address

Yahyanejad Hospital, Babol

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Ali bijani

Street address

Gangafroz Avenue

City

Babol

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, Babol
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**

Fatemehzahra Fertility & reproductive Health
Reseach Center

Full name of responsible person

Nargess Gholizadeh Pasha

Position

M.A/responsible of Reseach Center

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

Fatemehzahra Fertility & reproductive Health
Reseach Center - noshirvani street

City

Babol

Postal code

4719173716

Phone

+98 71112274881

Fax

+98 11 1227 4880

Email

ngh_pa@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Fatemehzahra Fertility & reproductive Health
Reseach Center

Full name of responsible person

Seddigheh esmaeilzadeh

Position

responsible of fatemehzahra Fertility & reproductive
Health Reseach Center/Gynecologist

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

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+98 11 1227 4881

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Email

sesmael@yahoo.com

Web page address

www.fatemehzahra.ir

Person responsible for updating data

Contact

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