Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 inform 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(transvers 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 undego 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, preeclamcia; surgery complications such as: server 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, defication 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
Fatemehzahra Fertility & reproductive Health Reseach Center - noshirvani steert
City
Babol
Postal code
4719173716
Phone
+98 11 1227 4881
Fax
+98 11 1227 4880
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