

# 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**

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4719173716

**Phone**

+98 71112274881

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**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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**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*