

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Evaluation the effect of gum chewing on the return of bowel function in cesarean-delivery patients.

#### Protocol summary

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##### Summary

We study the effect of gum chewing on the return of bowel movements after elective cesarean section. In a randomized clinical trial, 100 patients (from Rohani hospital, Bobol, Iran), who are candidates for cesarean section, are randomly and equally allocated to chewing gum or control groups after the operation. The patients in the gum-chewing group chew gum 3 times daily, each time for 15 minutes as soon as they become conscious till the time they pass flatus or defecate. Control group only receive after operation care. The first time to flatus passage, defecation, hearing of bowel sound and sensation of bowel movement are compared between groups.

##### Recruitment status

**Recruitment complete**

##### Funding source

Babol university of medical sciences

##### Expected recruitment start date

2010-06-06, 1389/03/16

##### Expected recruitment end date

2011-03-20, 1389/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008093902N2**

Registration date: **2011-03-06, 1389/12/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-03-06, 1389/12/15

##### Registrant information

###### Name

Farideh Mohsenzadeh

###### Name of organization / entity

Babol university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 1229 8582

###### Email address

##### Scientific title

Evaluation the effect of gum chewing on the return of bowel function in cesarean-delivery patients.

##### Public title

The effect of gum chewing on the return of bowel function in cesarean-delivery patients.

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: consent, uncomplicated term singleton pregnancies undergoing a planned caesarean section performed under spinal anaesthesia and by an gynecologist, transverse (horizontal) incision, at least NPO for 8 hours before surgery, receiving maximum four doses of antibiotic prophylaxis. Exclusion criteria: History of abdominal surgery, preeclampsia, diabetes, heart disease, postoperative complications such as uterine atonia, intra operative complications such as severe adhesions and blood transfusion during surgery, surgery lasted more than 60 minutes, receiving magnesium sulfate, history of malignancy, obstructive or inflammatory bowel diseases and injuries, excessive bowel manipulation, inability to chew gum.

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Babol university of medical sciences

**Street address**

Babol university of medical sciences

**City**

Babol

**Postal code**

4713838149

**Approval date**

2010-04-14, 1389/01/25

**Ethics committee reference number**

30/111

**Health conditions studied****1****Description of health condition studied**

Ileus

**ICD-10 code**

K56.0

**ICD-10 code description**

Paralytic ileus

**Primary outcomes****1****Description**

Gas passing

**Timepoint**

Every hour

**Method of measurement**

Asking from patients

**2****Description**

Hearing bowel sound

**Timepoint**

Every hour

**Method of measurement**

stethoscope

**3****Description**

Flatus passing

**Timepoint**

Every hour

**Method of measurement**

Asking from patients

**4****Description**

Sensation of bowel movement

**Timepoint**

Every hour

**Method of measurement**

Asking from patients

**5****Description**

Sensation of hunger

**Timepoint**

Every hour

**Method of measurement**

Asking from patients

**Secondary outcomes**

empty

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

Group A chewed sugarless gum for 15 minutes 3 times per day as soon as they recovered from anesthesia till they passed flatus or defecated

**Category**

Prevention

**2****Description**

Control group: Routine post-op care

**Category**

N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Babol university of medical sciences (Rohani hospital)

**Full name of responsible person**

Farideh mohsenzadeh

**Street address**

Babol university of medical sciences

**City**

Babol

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Babol university of medical sciences

**Full name of responsible person**

Amrollah Mostafazadeh

**Street address**

Babol university of medical sciences

**City**

Babol

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Babol university of medical sciences

**Full name of responsible person**

Shanaz Barat

**Position**

Obstetric & Gynecologist/faculty member

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Farideh Mohsenzadeh

**Position**

Midwifery msc/faculty member

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

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## Person responsible for updating data

#### Contact

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Farideh Mohsendeh

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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*