

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of chewing gum on the bloating after of cesarean section

#### Protocol summary

##### Summary

Evaluating the effect of chewing gum on post cesarean section bloating is the purpose of this study. In this double blinded randomized clinical trial which will take place between April 2015 to June 2015 in Sabzevar Mobini Hospital, Sabzevar, Iran. Eighty pregnant women who undergo cesarean section (elective or urgent) will be enrolled in this study and randomly divided into two groups (Case and Control group). One to 4 hours after the surgery, the patients are encouraged to chew gums each 6 hours four about 15 minutes. The control group will be monitored by usual surgery ward care. Study data will be gathered by observation and filling the questionnaire. Auscultation of intestinal sounds in both groups was documented every hour till complete return of bowel sounds. A researcher who is not aware of the study will perform the auscultation. Blinding performed for intravenous group and same as aid researcher to auscultation bowel sounds. Also, the time of first gas passage, defecation and sensation of bowel movements was documented.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015041221710N1**  
Registration date: **2015-06-28, 1394/04/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-28, 1394/04/07

##### Registrant information

###### Name

Batool Kamalimanesh

###### Name of organization / entity

Sabzevar University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 930 250 8805

##### Email address

kamalimaneshb1@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Sabzevar University of Medical Sciences

##### Expected recruitment start date

2015-05-05, 1394/02/15

##### Expected recruitment end date

2016-03-20, 1395/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of chewing gum on the bloating after of cesarean section

##### Public title

The effect of chewing gum on the bloating after of cesarean section

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Filling the informed consent form; Being nullipara; Lack of previous abdominal surgery; Lack of preeclampsia, Diabetes and cardiovascular disease; Being able to chew gum; Skin Pfannenstiel incision and uterine transverse incision; Using general anesthesia  
Exclusion criteria: Patients who are at risk of aspiration and ileus (such as radiation history, anastomosis and patients who are over sedated); Patients who are not willing to continue the study;

Surgical complication such as uterine atonia; Using intravenous antibiotics for more than four doses after surgery; Surgical complication at time of the surgery such as sever adhesions, blood transfusion, damaging the intestine or bladder; Patients who are discharged by their own decision; Surgery duration more than 90 minutes; Using magnesium sulfate (because of possible risk of nausea); History of any inflammatory or obstructive intestine disease; Intestine manipulation or damage

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 80

#### 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

Ethics Committee Sabzevar University of Medical Sciences

##### Street address

Sabzevar to Shahrood road, Sabzevar, Iran.

##### City

Sabzevar

##### Postal code

#### Approval date

2015-04-13, 1394/01/24

#### Ethics committee reference number

IR.MEDSAB.REC.1394.5

## Health conditions studied

### 1

#### Description of health condition studied

The bloating after of Cesarean

#### ICD-10 code

K91.9

#### ICD-10 code description

Postprocedural disorder of digestive system, unspecified

## Primary outcomes

### 1

#### Description

Time of first auscultation of bowel sounds

#### Timepoint

Every one hour after hearing the first sound

#### Method of measurement

Second

### 2

#### Description

Time of sensation of first bowel movement

#### Timepoint

Every one hour till the sensation of the first bowel movement

#### Method of measurement

Second

### 3

#### Description

Time of the first gas passage

#### Timepoint

Every one hour till the first gas passage

#### Method of measurement

Second

### 4

#### Description

Time of the first defecation

#### Timepoint

Every one hour till the first defecation

#### Method of measurement

Second

## Secondary outcomes

### 1

#### Description

Duration of Hospital stay

#### Timepoint

Duration between surgery and discharge

#### Method of measurement

Day

### 2

#### Description

Pain

#### Timepoint

Every 6 hours

#### Method of measurement

Visual Analogue Scale

## Intervention groups

1

### Description

Gum group, an oral chewing gum every 6 hours

### Category

Treatment - Drugs

2

### Description

No intervention

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Sabzevar Shahidan Mobini Hospital

#### Full name of responsible person

Batool Kamalimanesh

#### Street address

#### City

Sabzevar

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice Chancellor for research of Sabzevar University of Medical sciences

#### Full name of responsible person

Mohammad zadeh Mohammad

#### Street address

Building No.2, Fifth km Sabzevar SHahrood Road,  
Student Research Department, Sabzevar University of  
Medical Sciences, Sabzevar, Iran

#### City

Sabzevar

#### 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 of Sabzevar 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

Sabzevar University of Medical Sciences

#### Full name of responsible person

Batool Kamalimanesh

#### Position

MSc of Midwifery

#### Other areas of specialty/work

#### Street address

Sabzevar Shahidan Mobini Hospital, Sabzevar, Iran

#### City

Sabzevar

#### Postal code

#### Phone

+98 51 4441 9572

#### Fax

#### Email

kamalimaneshb1@medsab.ac.ir;

b.kamalimanesh@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Sabzevar University of Medical Sciences

#### Full name of responsible person

Batool Kamalimanesh

#### Position

MSc of Midwifery

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

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Sabzevar University of Medical Sciences

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Batool Kamalimanesh

#### Position

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#### Street address

Sabzevar Shahidan Mobini Hospital, Sabzevar, Iran

**City**

Sabzevar

**Postal code****Phone**

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**Fax****Email****Web page address****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*