

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 took place between April 2015 to June 2015 in Sabzevar Mobini Hospital, Sabzevar, Iran. Eighty pregnant women who undergo cesarean section (elective or urgent) will 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 performed 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 contest formy; 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

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Person responsible for updating data

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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