

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of gum chewing and coffee consumption on intestinal motility in caesarean sections

Protocol summary

Study aim

Due to contradictory evidence in reducing the duration of Ileus after cesarean section, this study was designed to determine the effect of chewing gum and coffee and compare the two dimensions after cesarean section.

Design

Clinical trial with control group, parallel groups, double-blind, randomized with color card, on 150 patients.

Settings and conduct

The research will be performance in Alavi Hospital in Ardabil. In the three groups studied, the time of feeling the bowel movements and the time of passage of the first gas and excretion between the groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous, age between 35-38 years, BMI in the normal range, gestational age between 37-42, elective cesarean section, without use of specific drugs and without history of chronic systemic diseases
Exclusion criteria: preterm delivery, multiple pregnancies, premature rupture of membranes, emergency cesarean section, body temperature above 38 degrees, severe anemia, history of surgery Abdominal other than cesarean section, allergic reaction to the materials used and inability to chew gum

Intervention groups

Patients were randomly divided into 3 groups based on the card color in the pocket: group 1 (women received turpentine gum 4 hours after surgery until the first defecation) 50 women, the second group (women 100 ml of coffee is given at 4-hour intervals starting from the second hour after surgery to the first bowel movement 3 times a day) 50 people and group 3 (control group) 50 people.

Main outcome variables

Time of first passage of the first gas of gut, Time of first passage of the first defecation, Time of first passage of the first the first gut sound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210113050028N1**

Registration date: **2021-02-12, 1399/11/24**

Registration timing: **prospective**

Last update: **2021-02-12, 1399/11/24**

Update count: **0**

Registration date

2021-02-12, 1399/11/24

Registrant information

Name

Noushin Mobaraki-asl

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 45 3323 5861

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-17, 1399/11/29

Expected recruitment end date

2021-04-18, 1400/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gum chewing and coffee consumption on intestinal motility in caesarean sections

Public title

Effect of gum chewing and coffee consumption on intestinal motility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI in normal range gestational age 37-42 Elective Cesarean section Do not use any special medicine No history of chronic systemic diseases

Exclusion criteria:

Preterm labour Multiple pregnancy premature rupture of memberan Emergency cesarean section (due to placental problems, chorioamnionitis, fetal distress, placental abnormalities, vaginal bleeding, etc.) Body temperature above 38 degrees Severe anemia History of abdominal surgery other than cesarean section Allergic reaction to the used materials Inability to chew gum

Age

From **13 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate the bias caused by the patient's knowledge and the clinical caregiver and evaluator, the patient is selected for the type of intervention and its possible impact on the research result of the study is done in a double-blind method. Given that the patient's choice and method of intervention is done using a color card, it is natural that the patient and the clinical caregiver and analyst will not interfere in choosing the type of intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Gynecology department, alavi hospital, Mogadas Ardabili Avenue,

City

Ardabil

Province

Ardabil

Postal code

5613974156

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.ARUMS.REC.1399.420

Health conditions studied

1

Description of health condition studied

Intestinal motility and ileus in caesarean sections

ICD-10 code

O99

ICD-10 code description

Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Intestinal motility

Timepoint

Patients will be visited every hour

Method of measurement

The time of the first bowel movements, the time of the first expulsion of gas, defecation and gut sound will be recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Chewing gum group: This group will chew 2 pieces of turpentine chewing gum 3 times a day (at least 3 hours, morning, noon, night) for a period of 15 minutes from 2 hours after surgery until defecation.

Category

Treatment - Other

2

Description

Intervention group 2 : Group 2 will be given 100 ml of coffee - 2 g (1 teaspoon) of decaffeinated coffee, without supplement (milk, sugar) - three times in day for at least 4 hours intervals until defecation after the start of the diet.

Category

Treatment - Other

3

Description

Control group: This group will not receive any intervention, only routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Nooshin Mobaraki_asl

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Varzesh Square, Mogadas ardabili Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Farhad Pourfarzi

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

No

Title of funding source

Ardabil University of Medical Sciences assistance of Research

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Jinous Gamissi

Position

Research expert, midwifery teacher

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Noushin Mobaraki-asl

Position

Assistant professor of Oncology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals and after the publication of the article

When the data will become available and for how long

Access period starts 12 months after the article are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

All documents and analyzes can be used only as a result of research after identifying individuals.

From where data/document is obtainable

Dr. nooshin mobaraki_asl, Ardabil University of Medical Sciences, alavi hospital, n.mobarak@aruma.ac.ir Jinous Gamissi, Ardabil University of Medical Sciences, alavi hospital, gamissijinous@gmail.com

What processes are involved for a request to access data/document

After receiving the email, depending on the volume and type of data request will be sent

Comments