

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effect of misoprostol and chewing gum on intestinal movements after cesarean delivery

#### Protocol summary

##### Study aim

Effects of misoprostol and gum chewing on intestinal motility after cesarean section

##### Design

This study is a single blind clinical trial.

##### Settings and conduct

324 pregnant women more than 18 years with single pregnancy candidate cesarean will enter in three intervention groups. The patient is not aware of the intervention type.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-45 years old; single pregnancy; candidate for elective cesarean section (non-emergency). Exclusion criteria: changing the type of anesthesia to the general; presence of clear peritonitis or sepsis; history of previous bowel surgery; thyroid disease; cardiovascular, blood and liver disease; inflammatory bowel disease; history of chronic constipation; history of misoprostol hypersensitivity; electrolyte imbalance; history of allergy to acetaminophen.

##### Intervention groups

We prescribe 600 milligram misoprostol rectal in cesarean after delivery placenta. The second group received chewing gum 2 hours after the chewing gum for up to 24 hours each day for 3 hours. The third group received suppository of placebo.

##### Main outcome variables

Effects of misoprostol and gum chewing on intestinal motility after cesarean section

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N74**

Registration date: **2018-04-13, 1397/01/24**

Registration timing: **retrospective**

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

##### Registration date

2018-04-13, 1397/01/24

##### Registrant information

###### Name

Fariba Farokhi

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-09-22, 1395/07/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of misoprostol and chewing gum on intestinal movements after cesarean delivery

##### Public title

Comparison of the effect of misoprostol and chewing gum on intestinal movements after cesarean delivery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age: 18-45 years old Single pregnancy pregnancy  
Candidate for elective cesarean section (non-emergency)

**Exclusion criteria:**

Changing the type of anesthesia to the general Presence  
of clear peritonitis or sepsis History of previous bowel  
surgery Thyroid disease Cardiovascular, blood and liver  
disease Inflammatory bowel disease, history of chronic  
constipation History of misoprostol hypersensitivity  
Electrolyte imbalance History of allergy to  
acetaminophen

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **324**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with random numbers

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The patient is not aware of the treatment received.  
Participant is blind.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee Arak University Of Medical Sciences

**Street address**

Vice chancellor for research, Payambar azam  
complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Approval date**

2016-08-22, 1395/06/01

**Ethics committee reference number**

IR.ARAKMU.REC.1395.207

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

Elective cesarean section

**ICD-10 code**

O82.0

**ICD-10 code description**

Delivery by elective caesarean section

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

Onset of intestinal movements

**Timepoint**

6 hours after surgery for 4 hours at intervals every 1  
hour

**Method of measurement**

Hearing

**2****Description**

First time the stool is removed after surgery

**Timepoint**

After surgery

**Method of measurement**

Observation

**3****Description**

Drug side effect

**Timepoint**

After surgery

**Method of measurement**

Physical examination

**Secondary outcomes**

empty

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

Intervention group: we prescribe 600 milligram  
misoprostol rectal in cesarean after eject placenta.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: The second group received chewing

gum 2 hours after the chewing gum for up to 24 hours each day for 3 hours.

**Category**

Treatment - Other

**3****Description**

Control group: The third group received placebo suppositories.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani hospital

**Full name of responsible person**

Dr Nazila Najdi

**Street address**

Taleghani hospital, Emam khomeini street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

najdi@arakmu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Arjmandzadegan

**Street address**

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

arjmandzadegan@arakmu.ac.ir

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

Yes

**Title of funding source**

Arak University of Medical Sciences

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

alikamaliir@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Nazila Najdi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Taleghani hospital, Emam khomeini street

**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
najdi@arakmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Arak University of Medical Sciences  
**Full name of responsible person**  
Pegah Eslami  
**Position**  
medicine student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Vice chancellor for research, Payambar azam  
complex, Basij square, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003

**Fax**  
+98 86 3222 2003  
**Email**  
peslami\_92@yahoo.com

## 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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

When we publish article in journal.

### When the data will become available and for how long

After the article is published

### To whom data/document is available

researcher in university

### Under which criteria data/document could be used

If there are additional questions

### From where data/document is obtainable

Dr Nazila Najdi

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

They have to write letters to the professors and the university

### Comments