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 misoprostoland 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
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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 squre, 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

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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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

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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
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