Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Kegel Exercises for Prevention and Treatment of Constipation and Flatulence in Antenatal and Postnatal.

Protocol summary

Study aim

The effect of Kegel exercise on the flatulence and constipation during pregnancy and after vaginal delivery and cesarean

Design

Controlled randomized clinical trial in two groups (intervention and control groups)

Settings and conduct

This study is a single-blind, randomized clinical trial conducted in Shahidan Mobini Hospital and Sabzevar Health Care Centers. Sampling is convenience. Participants Inclusion criteria were divided randomly into two case and control groups.Control group members are under prenatal care. In the case group, Kegel exercise is taught in addition to receiving routine care. The researcher tracks home exercise in the case group. Bloating and constipation severity in both groups is presented to the researcher by information A and B at the start of the study, 8 weeks after the start and 10 and 42 days after delivery.

Participants/Inclusion and exclusion criteria

Pregnant mothers healthy Minimum age 18 years olds Ability to read and write The desire to participate in the study Single pregnancy ; The presence of chronic medical conditions History of pelvic and reconstructive surgery in the genital and urinary system Taking antibiotics 2 weeks before study

Intervention groups

Kegel exercises: In the intervention group , Kegel exercise is taught, in addition to receiving routine care .This group is trained to perform Kegel exercise on a daily basis three times a day every 20-15 minutes for 8 consecutive weeks. Control group members are under prenatal care.the control group will also receive the conventional standard methods for improving constipation, such as increased fluid and fiber intake (celluloid material such as wheat and whole wheat, wheat bran, vegetables and fruits).

Main outcome variables

Constipation score; Bloating score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190427043386N1**
Registration date: **2019-05-14, 1398/02/24**
Registration timing: **prospective**

Last update: **2019-05-14, 1398/02/24**
Update count: **0**

Registration date

2019-05-14, 1398/02/24

Registrant information

Name

Saideh Mehrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4229 5284

Email address

saidehmehrabadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2020-02-18, 1398/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Kegel Exercises for Prevention and Treatment of Constipation and Flatulence in Antenatal and Postnatal.

Public title
The Effect of Kegel Exercises for Constipation and Flatulence

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant mothers healthy Minimum age 18 years olds Ability to read and write The desire to participate in the study Single pregnancy

Exclusion criteria:
The presence of chronic medical conditions History of pelvic and reconstructive surgery in the genital and urinary system Taking antibiotics 2 weeks before study

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **305**

Randomization (investigator's opinion)
Randomized

Randomization description
Each mothers will be given a code. They are divided into two groups A and B based on random numbers.The type of group will be written and placed inside the matte and numbered envelopes for Allocation Concealment. The envelopes will be opened in order of entry and will be specified the type of group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst will not be aware of the intervention and control groups and the participants in each group, and the data will be entered with the number of each participating and the type of group to which the participant has been assigned, is not specified. care is different from the principal investigator. Information is available to the researcher in groups A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Sabzevar, Asad Abadi Ave, Central Office of Medical Sciences

City
Sabzevar

Province
Razavi Khorasan

Postal code
9613873136

Approval date
2019-03-15, 1397/12/24

Ethics committee reference number
IR.MEDSAB.REC.1398.002

Health conditions studied

1

Description of health condition studied
Constipation

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description
Severity of constipation based on pregnancy constipation measurement scale

Timepoint
The severity of constipation is measured before and 8 weeks of the study, as well as 10 and 42 days after delivery.

Method of measurement
pregnancy constipation measurement scale

2

Description
Intensity of bloating

Timepoint
The severity of bloating is measured before and 8 weeks of the study, as well as 10 and 42 days after delivery.

Method of measurement
Visual analog scall and Clinical examinations

Secondary outcomes

1

Description
Severity of Anxiety based on Spielberger State-Trait Anxiety
Timepoint
The severity of Anxiety is measured before and 8 weeks of the study, as well as 10 and 42 days after delivery.
Method of measurement
Spielberger State-Trait Anxiety scale

Intervention groups

1

Description
Intervention group: This group is trained to perform Kegel exercise on a daily basis three times a day every 20-15 minutes for 8 consecutive weeks. Kegel exercise training is under the supervision of a Masters of Midwifery.Also, during the referral for prenatal care, they are again evaluated about how to do the exercise.
Category
Prevention

2

Description
Control group: Routine care alone
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahidan Mobini Hospital
Full name of responsible person
Azam Zarghi
Street address
Kashefi Ave, Shahidan Mobini Hospital, Sabzevar Town
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9613873136
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M.S@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Fereshte ghorat
Street address
Tohid Town, Sabzever Town
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8319
Email
info@medsab.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Saideh Mehrabadi
Position
Master of Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 23, Rahnamai 17, Sabzevar Town.
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9617878131
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Azam Zarghi

Position
Master of Nursing

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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Position
Master of Midwifery

Latest degree
Master

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available