

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

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+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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshte ghorat

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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

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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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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

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Saideh Mehrabadi

Position

Master of Midwifery

Latest degree

Master