Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study of the effect of Kegel exercises and conventional therapy vs in treating functional constipation in children

Protocol summary

Study aim

Investigating the effect of Kegel exercises on the treatment of children's constipation

Design

This clinical trial was conducted on 8to 18-year-old children with functional constipation, according to Rome IV, who referred to the pediatric section of Imam Reza Clinic in Shiraz, Iran, in 2022. The sample consisted of 64 children who were randomly assigned to either the intervention or the control group. In the control group, conventional therapy including diet training, defecation training, and polyethylene glycol (PEG) syrup (0.7 g/kg daily) was provided by a pediatrician (5). In the treatment group, in addition to conventional therapy, Kegel exercises were also taught to the child verbally and in writing by a pediatrician in the presence of their parents. Patients were examined 3 months after the intervention. Frequency of defecation, duration of Defecation, painful defecation, Assistance used for defecation, Incomplete emptying, Unsuccessful defecation and Abdominal pain were measured at the final week of the intervention compared to baseline.

Settings and conduct

patients who referred to the pediatric section of Imam Reza Clinic from September to December 2022, those with a history of more than six consecutive months of constipation were screened.

Participants/Inclusion and exclusion criteria

Age 8 to 18 years • Functional constipation according to Rome IV criteria • Willingness to participate

Intervention groups

Kegel exercise compared to children using only standard drug treatment.

Main outcome variables

Determining the amount of change in the number of bowel movements ؛ change in time spent on the toilet;change in the effort to empty painful stools ؛change in the feeling of incomplete emptying ؛unsuccessful attempts to defecate over 24 hours ؛abdominal pain in constipated children who perform Kegel exercises compared to children who only use standard medical treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230424057984N1**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **retrospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Narges Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 6524

Email address

ansary.narges@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

2022-03-21, 1401/01/01

Actual recruitment end date

2022-09-21, 1401/06/30

Trial completion date

empty

Scientific title

A comparative study of the effect of Kegel exercises and conventional therapy vs in treating functional constipation in children

Public title

A comparative study of the effect of Kegel exercises and conventional therapy vs in treating functional constipation in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

• Age 8 to 18 years Willingness to participate Parent(s) sign the informed consent Functional constipation according to Rome Iv

Exclusion criteria:

Severe delay in motor skills development Constipation caused by medicine Bowel surgery (except appendectomy) Endocrine and metabolic disorders (hypothyroidism, hypercalcemia, diabetes mellitus, diabetes insipidus) Neurological and psychiatric disorders (spina bifida, cerebral palsy, anorexia nervosa, autism, or PDD-NOS) Down syndrome Hirschsprung's disease

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were allocated to two groups by random block method with 8 blocks of size 8. The information was placed inside envelopes, which were sealed and labeled with random numbers provided by the Allocation Random Software. Blocking and allocation sequence of envelopes for concealment was done by a person not involved in the research.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Namazi Hospital

City

Shiraz

Province

Fars

Postal code

۱۳۳۱۱ – ۷۱۹۳۶

Approval date

2022-12-06, 1401/09/15

Ethics committee reference number

IR.SUMS.MED.REC.1401.438

Health conditions studied

1

Description of health condition studied

functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Frequency of defecation

Timepoint

At the beginning of the study (before the start of the intervention) then 3 months later

Method of measurement

Likert scale: 2 times a week, once a week, less than once a week, less than once a month

2

Description

Duration of defecation

Timepoint

At the beginning of the study (before the start of the intervention) then 3 months later

Method of measurement

Likert scale: less than 5 minutes, 5-10 minutes, 10-20 minutes

3

Description

Incomplete evacuation of stool

Timepoint

At the beginning of the study (before the start of the

intervention) then 3 months later

Method of measurement

Likert scale: never, rarely, sometimes, usually

4

Description

Abdominal pain

Timepoint

At the beginning of the study (before the start of the intervention) then 3 months later

Method of measurement

Likert scale: never, rarely, sometimes, usually

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group: The basic treatment including diet training, defecation training and polyethylene glycol syrup was used. In this way, 0.7 g/kg of polyethylene glycol syrup was given daily. Beside that, toilet training and diet were also done by a pediatrician

Category

Treatment - Other

2

Description

Intervention group: Intervention group: in addition to 0.7gr / kg daily PEG syrup and toilet training and proper diet training, Kegel exercises were also taught to the child by a pediatric specialist in the presence of their parents, verbally as well as written form.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric section of Imam Reza Clinic

Full name of responsible person

Narges Ansari

Street address

Namazi Hospital

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Phone

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Email

Ansary.narges@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hashem Hashempur

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hashempur@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hadi Imaniyeh

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Pediatric gastroenterologist

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Narges Ansari

Position
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Latest degree
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Person responsible for updating data

Contact

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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
"Standard" by van Engelenburg et al. was conducted from December 2009 to May 2014 as a multicenter randomized trial on 53 children (age 5-16 years) with functional constipation based on Rome III criteria in Dutch hospitals.

When the data will become available and for how long
Three to four months

To whom data/document is available
Three to four months after the results are published

Under which criteria data/document could be used
For all people

From where data/document is obtainable
ansary.narges@yahoo.com Number 09133176480

What processes are involved for a request to access data/document
After 3 months of treatment, the success rate of the treatment was compared between the two groups before and after the study.

Comments
It is suggested that studies in this direction be carried out in multicenter in patients with functional constipation with different severities.