

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of pelvic physiotherapy in children With functional constipation compared with standard medical care

Protocol summary

Study aim

Comparison of the effect of pelvic physiotherapy with standard medical care on functional constipation in children

Design

Clinical trial, interventional, parallel groups, single blind, quality, Quadratic block randomization

Settings and conduct

Outpatient patients referred to gastroenterology clinic of Shahid Beheshti hospital of Kashan University of Medical Sciences are first visited and examined by pediatric gastroenterologist. Questionnaires are prepared and then randomly enrolled into two groups. The group is treated with polyethylene glycol as standard drug treatment and the second group is given pelvic physiotherapy.

Participants/Inclusion and exclusion criteria

1. Children 6 to 15 years 2. Children with chronic functional constipation

Intervention groups

Pelvic physiotherapy group and standard medical care group (recipient of polyethylene glycol powder)

Main outcome variables

Pediatric Constipation Score

General information

Reason for update

Due to the postponement of the recruitment, the recruitment dates was also corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191111045403N1**
Registration date: **2020-02-01, 1398/11/12**
Registration timing: **prospective**

Last update: **2020-02-15, 1398/11/26**

Update count: **1**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Amin ali Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

rahimi-a@mail.kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-04-08, 1399/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of pelvic physiotherapy in children With functional constipation compared with standard medical care

Public title

Effectiveness of pelvic physiotherapy in constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children With functional constipation children in 5 -15 old years

Exclusion criteria:
 Children with metabolic and endocrine diseases such as hypothyroidism, diabetes mellitus, diabetes mellitus and hypercalcemia, etc. Children with neurological or psychiatric illnesses such as spina bifida, cerebral palsy, anorexia nervosa, autism, neurofibromatosis, etc. Children with intestinal disease such as Hirschsprung's disease Children with Down Syndrome A history of intestinal surgery Children taking constipation drugs (anticholinergics, phenytoin, antidepressants, chemotherapy drugs such as vincristine, etc.) Children with fecal impaction Patients with a specific diet History of pelvic physiotherapy due to bladder or bowel problems during the past 3 months Perform any other remedies for constipation during the study Other Causes of Constipation, such as Scleroderma, Sexual Abuse, Cystic Fibrosis, and Dietary Protein Allergies

Age
 From **6 years** old to **15 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **68**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Samples will be selected by simple non-probability sampling method and then allocated into two groups by four-block randomization method.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Allocations were randomly assigned to two groups using computer software previously specified by the statistical specialist and patients would be assigned to either group A or group B, outcome assessor and data analyzer Which group of patients received drug treatment or physiotherapy is not known. This study is a unilateral blinded researcher.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address
 Faculty of Medicine, Kashan University of Medical Sciences, pezeshek Blvd., 3km of Ravand Road

City
 Kashan

Province
 Isfahan

Postal code
 88715973474

Approval date
 2019-10-06, 1398/07/14

Ethics committee reference number
 IR.KAUMS.REC.1398.040

Health conditions studied

1

Description of health condition studied
 Functional constipation in children

ICD-10 code
 K59.09

ICD-10 code description
 constipation

Primary outcomes

1

Description
 Pediatric Constipation Score

Timepoint
 At the beginning of the study(before intervention) and at 2 and 6 months after intervention

Method of measurement
 Pediatrics Incontinence/Constipation Score Questionnaire(PICS)

Secondary outcomes

1

Description
 Quality of life score

Timepoint
 At the beginning of the study(before intervention) and at 2 and 6 months after intervention

Method of measurement
 Based on the Quality of Life Questionnaire in Constipation Patients (PAC-QOL)

2

Description
 Abdominal pain score

Timepoint
 At the beginning of the study (before intervention) and at 2 and 6 months after intervention

Method of measurement
 Abdominal pain based on the Visual Analog Scale and

3

Description

Prebaseline pelvic floor muscles activity

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Surface Electromyography Based on millivolt

4

Description

Postbaseline pelvic floor muscles activity

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Surface Electromyography Based on millivolt

5

Description

Endurance of pelvic floor muscles

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Surface Electromyography Based on millivolt

6

Description

Strength of pelvic floor muscles

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Surface Electromyography Based on millivolt

7

Description

Pediatric Fecal Incontinence Scale

Timepoint

At the beginning of the study(before intervention) and at 2 and 6 months after intervention

Method of measurement

Pediatrics Incontinence/Constipation Score Questionnaire(PICS)

Intervention groups

1

Description

Intervention group: Pelvic Physiotherapy Receiving Group

Category

Treatment - Other

2

Description

Intervention group: Group receiving drug therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty Gastroenterology Clinic Shahid Beheshti Hospital Kashan University of Medical Sciences

Full name of responsible person

Abbas Taghavi Ardakani; Seyed Ramin Madani

Street address

Faculty of Medicine, Kashan University of Medical Sciences, pezesk Blvd., 3km of Ravand Road

City

Kashan

Province

Isfahan

Postal code

88715973474

Phone

+98 31 5562 1550

Email

medicine@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafsheh

Street address

Faculty of Medicine, Kashan University of Medical Sciences, pezesk Blvd., 3km of Ravand Road

City

Kashan

Province

Isfahan

Postal code

88715973474

Phone

+98 31 5510 9999

Email

medicine@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Isfahan

Postal code

88715973474

Phone

0098 31 55540021-25

Email

Rahimi-a@mail.kaums.ac.ir

Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Amin Ali Rahimi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Faculty of Medicine, Kashan University of Medical Sciences, Medical Blvd., 3km of Ravand Road

City

Kashan

Province

Isfahan

Postal code

88715973474

Phone

0098 31 55540021-25

Email

Rahimi-a@mail.kaums.ac.ir

Contact**Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Amin Ali Rahimi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Faculty of Medicine, Kashan University of Medical Sciences, pezeshek Blvd., 3km of Ravand Road

City

Kashan

Province

Isfahan

Postal code

88715973474

Phone

0098 31 55540021-25

Email

Rahimi-a@mail.kaums.ac.ir

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

Kashan University of Medical Sciences

Full name of responsible person

Amin Ali Rahimi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Faculty of Medicine- Kashan University of Medical Sciences- pezeshek Blvd- 3km of Ravand Road

City

Kashan

Province**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