Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying The Effect of Wheat Germ on Functional Constipation in Children Aged 10 to 14 Years :Single-Blind Randomized Clinical Trial

Protocol summary

Study aim

Overall objective: Determine the effect of wheat germ on functional constipation in children aged 10–14. Specific objectives (compare between groups): - Prevalence of functional constipation - Prevalence of: straining, lumpy/hard stools (Bristol), incomplete evacuation, anorectal obstruction/blockage, manual maneuver >once/week, <3 bowel movements/week, abdominal pain and bloating, fecal incontinence - Mean bowel movements/week and mean stool consistency score (Bristol) - Side effects of pidrolax vs. wheat germ

Design

This is a randomized, single-blind, controlled clinical trial with a factorial design involving 110 patients. Random assignment was performed by placing 110 black and white cards into a container and randomly drawing one card for each patient.

Settings and conduct

This clinical trial compares polyethylene glycol (1 g/kg) plus 15 g of wheat germ daily versus polyethylene glycol (1 g/kg) alone over 12 weeks in children aged 10–14 with functional constipation from the Imam Ali Clinic. It is single-blind, with patients unaware of their group, and all medication packaged identically.

Participants/Inclusion and exclusion criteria

- Providing informed consent - Diagnosis of functional constipation based on ROME IV criteria - Age 10 to 14 years - No use of laxatives in the preceding 4 weeks - Absence of hypothyroidism, fibrocystic disease, or intellectual disability - No clinical history of gastrointestinal disorders

Intervention groups

One group receives 1 g polyethylene glycol per dose (Sepidaj Company) plus 15 g wheatgrass daily; the control group receives 1 g polyethylene glycol daily. Treatment duration is 12 weeks.

Main outcome variables

If positive results are obtained regarding wheat germ's effect on functional constipation in children aged 10–14, it could serve as a suitable, side-effect- free alternative for better management of this condition.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260713070180N1**
Registration date: **2026-10-19, 1405/07/27**
Registration timing: **prospective**

Last update: **2026-10-19, 1405/07/27**
Update count: **0**

Registration date

2026-10-19, 1405/07/27

Registrant information

Name
Leila Zolfaghari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3225 2416
Email address
leila.zolfaghari79@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-24, 1405/08/02

Expected recruitment end date

2026-11-23, 1405/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Studying The Effect of Wheat Germ on Functional Constipation in Children Aged 10 to 14 Years :Single-Blind Randomized Clinical Trial

Public title
The Effect of Wheat Germ on Functional Constipation in Children Aged 10 to 14 Years

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
informed consent to participate in the study Diagnosis of a functional disorder based on ROME IV criteria (meeting at least 2 of the 6 ROME IV criteria). Ages 10 to 14

Exclusion criteria:
No use of laxatives in the preceding 4 weeks - Absence of hypothyroidism, fibrocystic condition, and intellectual disability. - No clinical history of gastrointestinal disease (celiac disease, inflammatory bowel disease, food allergy, or gastrointestinal surgery)

Age
From **10 years** old to **14 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual Simple Randomization Participants will be assigned to two groups—an intervention group and a control group, each consisting of 55 individuals—using a random allocation method. To achieve this, 110 black and white cards will be mixed together in a container, and one card will be drawn at random for each patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient is unaware of the type of intervention and medication, and both groups receive the medication in identical packages.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Shahrekord, Rahmatieh, Shahrekord University of Medical Sciences Educational Complex

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2026-06-27, 1405/04/06

Ethics committee reference number
IR.SKUMS.MED.REC.1405.087

Health conditions studied

1

Description of health condition studied
Functional constipation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determining the effect of wheat germ on functional constipation in children aged 10 to 14 years.

Timepoint
Participants will be assessed for functional constipation every 10 days using the Rome IV criteria.

Method of measurement
Stool consistency and form will be assessed using the Bristol scale; dosage adjustments will be made based on these findings and recorded in each individual's questionnaire.

Secondary outcomes

1

Description
Defecation with a sensation of incomplete evacuation

Timepoint
Every 10 days

Method of measurement
Entry into each participant's personal questionnaire

2

Description

Defecation with lumpy or hard stools

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

3

Description

Fecal incontinence

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

4

Description

Defecation with a sensation of anorectal obstruction or blockage

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

5

Description

Abdominal pain

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

6

Description

Straining during defecation

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

7

Description

Manual maneuvers to facilitate defecation

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

8

Description

Bowel movement frequency of fewer than 3 times per week

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

9

Description

Adverse events associated with the administration of Pidrolax and wheat germ

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

10

Description

Assessment of stool consistency and form

Timepoint

Every 10 days, based on the Bristol Stool Form Scale

Method of measurement

Entry into each participant's personal questionnaire

11

Description

Bowel movement frequency per week

Timepoint

Every 10 days

Method of measurement

Entry into each participant's personal questionnaire

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

2

Description

Control group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali (AS) Subspecialty Clinic

Full name of responsible person

Leila Zolfaghari

Street address

Shahrekord, Shariati Boulevard, Imam Ali (AS) Specialized Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816854633

Phone

+98 38 3224 2696

Email

leila.zolfaghari79@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Ali Hasanpoor

Street address

Shahrekord, Kashani Boulevard, University Headquarters, Building No. 2

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Email

research@skums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Leila Zolfaghari

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Isfahan, Imam Khomeini Street, Kowsar Residential Complex, Salman Farsi Boulevard, Roz Alley (7), No. 71, 2nd Floor

City

Esfahan

Province

Isfehan

Postal code

8195618791

Phone

+98 31 3324 3014

Email

leila.zolfaghari79@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Hassan Talakesh

Position

Faculty Member / Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahrekord – Parastar Street – Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816854633

Phone

+98 38 3110 7000

Email

talakesh.h@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Leila Zolfaghari

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Isfahan, Imam Khomeini Street, Kowsar Residential Complex, Salman Farsi Boulevard, Roz Alley (7), No. 71, 2nd Floor

City

Esfahan

Province

Isfehan

Postal code

8195618791

Phone

+98 31 3324 3014

Email

leila.zolfaghari79@gmail.com

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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

A subset of the data, including the Pidrolax dose and the effects of wheat germ on functional constipation and its adverse effects, will be shared

When the data will become available and for how long

The access period begins 6 months after publication of the results

To whom data/document is available

Researchers affiliated with academic and scientific institutions, medical students, and researchers employed in the pharmaceutical industry

Under which criteria data/document could be used

Scientific research within the pharmaceutical industry can be employed to establish new protocols applicable to the administration of wheat germ in the treatment of pediatric functional constipation. Furthermore, the data are accessible to academic researchers.

From where data/document is obtainable

To obtain the data, individuals may submit their requests via email to Leila Zolfaghari at leila.zolfaghari79@gmail.com

What processes are involved for a request to access data/document

Requests will be reviewed by the undersigned, Leila Zolfaghari, and, following verification of the identity of the individual or organization making the request by the Hajar Clinical Research Center and the relevant bodies at Shahrekord University of Medical Sciences, a response will be provided within approximately two months.

Comments