

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of treatment of chronic constipation using combination of Rosa damascene and brown sugar in comparison with polyethylene glycol in children over 12 months old

Protocol summary

Study aim

Comparison of the effect of using the combination of Mohammadi red rose and red sugar with polyethylene glycol in the treatment of constipation in children over 12 months in Shiraz

Design

Clinical trial with control group, with cross-groups, double-blind, randomized, phase 2 on 100 patients. Block randomization has been used.

Settings and conduct

In this study, based on a pilot project and two blind heads, 100 children over 12 months referred to Imam Reza Specialized and Subspecialty Clinic of Shiraz University of Medical Sciences, who were diagnosed with Functional Chronic Constipation based on their history and physical examination. They will be investigated after obtaining informed consent from the parents.

Participants/Inclusion and exclusion criteria

Admission: Children over 12 months of age with Functional Constipation with Conscious Parental Satisfaction
Withdrawal: Patients who have an underlying disease such as hypothyroidism based on the history and physical examination

Intervention groups

In the test group, 50 children used the combination of Mohammadi rose and red sugar as a treatment for constipation, and in the control group of 50 children, they used polyethylene glycol as a treatment for constipation.

Main outcome variables

Defecation less than or equal to two times a week, Fecal incontinence equal or more than once a week, History of excessive stool retention, History of hard or painful defecation, Large fecal mass in the rectum, History of thick stools that may block the toilet, Appetite disorder, Bad Breath, Abdominal pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090908002434N8**

Registration date: **2020-11-15, 1399/08/25**

Registration timing: **retrospective**

Last update: **2020-11-15, 1399/08/25**

Update count: **0**

Registration date

2020-11-15, 1399/08/25

Registrant information

Name

Mohammad Hadi Imanieh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4298

Email address

imaniehm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2020-11-14, 1399/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of treatment of chronic constipation using combination of Rosa damascene and brown sugar in comparison with polyethylene glycol in children over 12 months old

Public title

Evaluation of treatment of chronic constipation using combination of Rosa damascene and brown sugar in comparison with polyethylene glycol in children over 12 months old

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children over 12 months of age with Functional Constipation no underlying disease such as Hirschsprung's disease and metabolic and hypothyroidism

Exclusion criteria:

Age

From **12 months** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible people in the study will be randomly assigned to two groups based on a double-blind study. The random allocation will be blockchain, Four-person blocks that we will have 25 blocks. Twenty-five blocks of four people are selected with random allocation software and people will be assigned to two groups based on these blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, polyethylene glycol syrup in the control group and rose + red sugar syrup based on the evidence of traditional medicine with great effect in the treatment of constipation in the experimental group was used. For this purpose, new patients referred to Imam Reza Clinic of Shiraz University of Medical Sciences After examining and diagnosing constipation, the doctor writes the title of the medicine to treat constipation on the prescription sheet. The patient's initial information is recorded by staff who are also blind, and then the patient is referred to the clinic pharmacy for medication. There, the pharmacy staff, who are blind, give the patient a drug coded by the pharmacist based on a four-item random block table.

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

Zand Blvd

City

Shiraz

Province

Fars

Postal code

7134874853

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.SUMS.MED.REC.1399.368

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

constipation

Primary outcomes

1

Description

Defecation less than or equal to two times a week

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

2

Description

Fecal incontinence equal or more than once a week

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

3

Description

History of stool retention

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

4

Description

History of hard or painful defecation

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

5

Description

Large fecal mass in the rectum

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

6

Description

History of thick stools that may block the toilet

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

7

Description

Appetite disorder

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

8

Description

Bad Breath

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

9

Description

Abdominal pain

Timepoint

Start treatment, two weeks later and four weeks later

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"intervention group" rosemary extract and red sugar based on the matching of the desired active ingredient in which 1cc / kg / day of rose syrup and rose with 1cc / kg / day of polyethylene glycol 40 syrup % Are equal and in terms of appearance both syrups are the same and are in the same containers are used as a treatment for constipation. After receiving the initial dose, at the end of the second week after treatment, they will be examined by a therapist and Basic information is recorded in the questionnaire. If a clinical response is established, treatment with the same dose will continue for another two weeks, and if no response to treatment is observed, treatment is increased to 2cc / kg / day and patients will be re-examined at the end of the fourth week. The fourth week and the final visit, the patients will be re-evaluated. Patients who received 1cc / kg / day of the drug and the dose was not increased will be re-evaluated for symptom response, and patients who received 2cc / kg / day of anti-constipation therapy for response to treatment Will be evaluated.

Category

Treatment - Drugs

2

Description

Control group: 50 children use polyethylene glycol as a treatment for constipation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Reza Specialized and Subspecialty Clinic of Shiraz University of Medical Sciences

Full name of responsible person

Abbas Avaz Pour

Street address

Namazi Square, Shiraz, Zand St., Fars Province,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Abbas Rezaeianzadeh

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Shiraz university of medical sciences(central building), Zand Street, Shiraz, Fars

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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

Abbas Avaz Pour

Position

Fellowship of Pediatric Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

Mohammad Hadi Imanieh

Position

Professor of Pediatric Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

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Heidar Safarpour

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General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After the research and publication of the article, information about the main outcome and the

interventions will be shared.

When the data will become available and for how long

At the end of the study since 2021

To whom data/document is available

All physicians and researchers related to the field of pediatrics

Under which criteria data/document could be used

For therapeutic and research use, information will be provided to all physicians and researchers

From where data/document is obtainable

Shiraz Namazi Hospital, Pediatric's Department Office, Pediatric Gastroenterology Department

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

By referring to Shiraz Namazi Hospital, Pediatric's Department Office, Pediatric Gastroenterology Department

Comments