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)

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+98 71 1647 4298

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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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abbas.avazpour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Shiraz university of medical sciences(central building), Zand Street, Shiraz, Fars
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7134874853
Phone
+98 71 3235 7282
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vcrdep@sums.ac.ir
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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Person responsible for updating data

Contact
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General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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safarpourh@sums.ac.ir

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