

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the effectiveness of Water Enema with common medical therapy in alleviating Constipation in Chronic Constipation patients

Protocol summary

Study aim

The main goal of this study is to compare two alternative treatment options for chronic constipation, namely water enema and common medical therapy. A comparison will be conducted on the level of symptoms alleviation, such as the frequency of bleeding or the pain severity, and the perceived improvement in quality of life. Analysing the results of this study will enable the clinicians to select a more appropriate strategy for treating chronic constipation and to improve the patients' overall quality of life.

Design

This will be an unblinded clinical trial, randomized by application of the sealed envelope method. It will have parallel design including a control group. This clinical trial will have a sample size of at least 60 patients.

Settings and conduct

The cases of chronic constipation which are referred to the Bojnourd hospitals during the defined interval will be enrolled in our study. Opportunistic sampling and randomization via sealed envelope method will be carried out.

Participants/Inclusion and exclusion criteria

The presence of chronic constipation (having two or fewer defecations per week)

Intervention groups

The first group consists of patients who are treated with water enema (150 to 200 milliliter of water). Patients in second group undergo medical therapy with MgOH syrup and Bisacodyl Suppositories.

Main outcome variables

Alleviation of symptoms associated with chronic constipation (such as pain severity and frequency of bleeding)/ increase in the number of defecations in each week will be compared among the two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201130049547N1**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Mohsen Rakhsha

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3151 3012

Email address

sadafdelshad.98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Water Enema with common medical therapy in alleviating Constipation in Chronic Constipation patients

Public title

Effects of Water Enema on Chronic Constipation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All the patients suffering from signs of chronic constipation (two or fewer defecations in a week)can be included in the study

Exclusion criteria:**Age**

From **15 years** old to **95 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using the “sealed envelope method” . Every participating clinician are provided with an identical set of envelopes which contain either of the two treatment options. Each of the two options have the same in the number in the sets. Each clinician would draw one envelope from the set for each patient and continue the patient’s treatment according to the drawn result.

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 North Khorasan University of Medical Sciences

Street address

North Khorasan University of Medical Sciences;
Shahriar St; Bojnurd; North Khorasan Province

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Postal code

9413875199

Approval date

2020-08-23, 1399/06/02

Ethics committee reference number

IR.NKUMS.REC.1399.062

Health conditions studied**1****Description of health condition studied**

Constipation

ICD-10 code

ME05.0

ICD-10 code description

Constipation is an acute or chronic condition in which bowel movements occur less often than usual or consist of hard, dry stools that are often painful or difficult to pass. Here constipation other than specifically described elsewhere such as in here.

Primary outcomes**1****Description**

An increase in the number of defecations : more than two defecations per week

Timepoint

Three months and Six months after the intervention

Method of measurement

Patients’ Inquiry regarding the number of defecations

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Water Enema recipients Patients will enema 150 to 200 cc of water through the anus daily with Powar. During the 6-month study period, the patient is advised to use only the treatment provided.

Category

Treatment - Devices

2**Description**

Control group: The control group will use the usual treatment for patients with constipation, which includes drug treatment (30 cc of Magnesium Hydroxide syrup every 12 hours and daily Bisacodyl suppository).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person

Mohsen Rakhsha

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Mohsen Rakhsha

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Person responsible for updating data

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Other areas of specialty/work

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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

All personal data is shared after deleting the profile

When the data will become available and for how long

Access period starts 9 months after the results are published

To whom data/document is available

Researchers working in academic institutions and public and private scientific research centers

Under which criteria data/document could be used

Any analysis and use of this data is permitted.

From where data/document is obtainable

dr.rakhsha@yahoo.com

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

Obtaining the permit of the deputy of research and technology of North Khorasan University of Medical Sciences.

Comments