

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparative study on the effectiveness of Golghand (Persian traditional medicine product) with magnesium hydroxide in the improvement of adult constipation

Protocol summary

Study aim

Compare the frequency of defecations in both groups before the starting of the Intervention.

Design

Randomized clinical trial with parallel groups, control group, blindness has not been performed Sample size: Two groups of 28 people

Settings and conduct

Procedure: Patients complained of chronic constipation will be included in the study after receiving sufficient information and obtaining consent. In the first visit, the consent form, the demographic questionnaire and the checklist for Gastrointestinal mezaj form are completed for patients. Patients were divided into two groups based on random blocks: A-Common Medicinal Treatments (Magnesium Hydroxide) B-Treatment with Golghand Potion In the first two weeks, patients will take medication and in the second two weeks, patients should discontinue the medication and be monitored without medication. This study was conducted at Sayyad Hospital in Gorgan.

Participants/Inclusion and exclusion criteria

Inclusion criterias: age over 20, Roman criterias 3, no laxative, patient satisfaction - Exclusion criterias: use of other medications, history of any systemice and metabolic diseases

Intervention groups

The intervention is divided into two groups of 28 people. 28 people will use golghand and 28 people will use magnesium syrup.

Main outcome variables

Frequency of defecation ;The amount of straining in the defecation; Frequency of Lumpy or hard stool; Sensation of incomplete evacuation after defecation;use the Manual maneuvers to facilitate in defecation ; Occurrence of stool; Other Symptoms ; side effect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180114038354N1**

Registration date: **2019-07-21, 1398/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

Registration date

2019-07-21, 1398/04/30

Registrant information

Name

Ghorbanoghli Sayeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-06, 1398/04/15

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the effectiveness of Golghand (Persian traditional medicine product) with magnesium hydroxide in the improvement of adult constipation

Public title

The effect of Golghand in the improvement of constipation in adults

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion Criteria : 1-age over 20 years 2. Have at least 2 of the following criteria; - Straining during at least 25 percent of defecations - Lumpy or hard stools in at least 25 percent of defecations -Sensation of incomplete evacuation for at least 25 percent of defecations - Sensation of anorectal obstruction/blockage for at least 25 percent of defecations -Manual maneuvers to facilitate at least 25 percent of defecations -Fewer than three defecations per week 3. during the last month, Without the use of laxatives, rarely have soft stool 4. Patient satisfaction to participate in the study

Exclusion criteria:

Exclusion criterias: 1- Use medications Anti-seizures, Carbamazepine, Phenobarbital, Phenytoin, Anti-neoplastic, Calcium channel blockers: Verapamil, Diuretics: Forzamide, Anti-epileptic drugs, Anti-epileptic drugs, Anti-epileptic drugs. , 5-HT antagonists, NSAIDs: ibuprofen, opioid. 2. History of mechanical and False intestinal obstruction based on previous colonoscopy or radiography or history 3 - Metabolic and endocrine diseases such as Diabetes, Hyperthyroidism and Hypothyroidism, Hypercalcemia, Hypokalemia, Pan-Hypopyothelium, Pheochromocytoma, Porphyria 4. Neurological disease and myopathic amyloidosis, autonomic neuropathy, Chagas disease, dermatomyositis, multiple sclerosis, Parkinson's disease, systemic progressive sclerosis, spinal cord injury based on biography and history 5-Special surgical and special medical conditions such as inability to move, history of Intestine surgery, ... 6. Endoscopy and radiology report in the last 5 years on abnormalities, malignancy, IBD and hemorrhoids 7-Patients with abnormal Hgb, TFT, Ca, and ESR. 8-Patients with HTN or Diabetes 9 -Patients with Asthma and Bronchitis 10.-Patients with Renal failure 11. Pregnant and nursing women

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The initial selection of the samples will be available as a sampling from among the people referring to the Sayyid

Gorgan educational center and observing the entry criteria. The allocation of 56 people to two groups of 28 was random

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 Gorgan university of medical sciences

Street address

No 114, Dokhniyat 3 , Dokhniyat blvd, Gorgan town

City

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Province

Golestan

Postal code

4917953776

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.Goums.Rec.1397.276

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

constipation in adult

ICD-10 code

K59.0

ICD-10 code description

Constipation

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

Frequency of defecation in the week

Timepoint

Frequency of defecation in the subjects before the intervention and in the 14th day and 28th day after starting intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

The amount of straining in the defecation

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

2

Description

Frequency of lumpy or hard stools

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

3

Description

Sensation of incomplete evacuation after defecation

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

4

Description

frequency of Manual maneuvers to facilitate

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

5

Description

Occurrence of stool

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

6

Description

Other related symptoms

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

7

Description

side effect

Timepoint

Before the beginning of the Intervention and in the 14th day and 28th day after starting the Intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: They will use Golghand, Golghand is an Iranian traditional medicinal that consists of rose petals and honey, which is provide by Niaku Gorgan Pharmaceutical Company. The chemical composition of the analysis is as follows (100 grams of Golghand): 39.5 g (39%) regenerated Sugars - 19.5 g Sucrose (19%) - 10.2 g (10%) Fructose - 17.5 g total volatile oil 17%) - Geraniol 7 mg (007%) - Citroneulol 5 mg (005%) . The dosage is 20 grams daily for pationts.they use 10 grams before lunch and 10 grams before dinner with a glass of water. Patients will take medication for two weeks.

Category

Treatment - Drugs

2

Description

Control group: Participants in the control group will receive magnesium hydroxide syrup. This is provided from the Souha Pharmaceutical Company. this group receives magnesium syrup 40 cc (According to the standard dosage of 30-60 cc in Iran's generic drugs book) In two divided doses, morning (20 cc)and night Before sleeping (20 cc).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Sayyad Shirazi Medical Education Center

Full name of responsible person

Sayeh Ghorbanighli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Vice-chancellor of Research and Technology of
Gorgan University

Street address

Vice-chancellor of Research and Technology, Gorgan
University of Medical Sciences, 5 Km Gorgan, Sari
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Golestan

Postal code

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Phone

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Email

Info@goums.ac.ir

Web page address

http://goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Sayeh Ghorbanoghli

Position

Residence

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Information on the main outcomes and non-core outcomes will be published and analyzed and analyzed

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

all people

Under which criteria data/document could be used

There is no limit for using the results Naming resources

From where data/document is obtainable

Sayeh Ghorbanoghli dr.ghorbanoghli@goums.ac.ir

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

It will be answered as soon as possible

Comments