# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Comparative study on the effectiveness of Golghand (Persian traditional medicine product) with magnesium hydroxide in the improvement of adalt 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**

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Iran (Islamic Republic of)

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**Email address**

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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 adalt 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:**
Exclousion 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 commeitee of Gorgan university of medical scinces
**Street address**
No 114,Dokhniyat 3 , Dokhaniyat blvd, Gorgan town
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**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 internvention and in the 14th day and 28th day after startinig 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
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Vice-chancellor of Research and Technology, Gorgan University of Medical Sciences, 5 Km Gorgan, Sari Road
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**Web page address**
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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**
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**
Residense
**Latest degree**
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**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

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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**