

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Examination of the efficiency and safety of the herbal capsule containing aloe vera and flax leaves for curing constipation and comparing it with magnesium hydroxideComparison wi

Protocol summary

Study aim

Examination of the efficiency and safety of the herbal capsule containing aloe vera and flax leaves for curing constipation and comparing it with magnesium hydroxide; and Achieving a beneficial, cheap, and less side effect drug.

Design

A clinical trial was conducted on 100 patients in two groups of control and treatment based on community and pragmatic, with parallel, blind, randomized, randomized, 50-person groups

Settings and conduct

Patients are required to use herbal capsule or magnesium hydroxide twice daily for 2 weeks and then answer the questionnaire .

Participants/Inclusion and exclusion criteria

Inclusion criteria: obtaining the informed consent of the patient; have not been treated with any form of laxative drugs; diagnosis of constipation has been confirmed by a physician. Exclusion criteria: patients' age is not less than 12 and more than 80 years; the patient is not pregnant .

Intervention groups

Herbal capsule for 2 weeks and twice daily in the treatment group and Magnesium hydroxide for 2 weeks and twice daily in the control group

Main outcome variables

Study of the number of fecal excretions, the frequency of soft stool excretion and examination of the pain score during stool excretion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N38**
Registration date: **2018-07-17, 1397/04/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examination of the efficiency and safety of the herbal capsule containing aloe vera and flax leaves for curing constipation and comparing it with magnesium hydroxideComparison wi

Public title

Effect of the herbal capsule containing aloe vera, flax leaves for curing constipation and comparing it with magnesium hydroxide
Comparison with Magnesium Hydroxide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

obtaining the informed consent of the patient; have not been treated with any form of laxative drugs; diagnosis of constipation has been confirmed by a physician.

Exclusion criteria:

Age

From **12 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Accidental assignment to intervention and control groups using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient groups are divided into two groups, and other researchers involved in the study are not known to have any type of control or intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah Medical Sciences University الله

Street address

Mulla sadra Street

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۹۱۵۳۷۱

Approval date

2017-12-25, 1396/10/04

Ethics committee reference number

IR.BMSU.REC.1396.104

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Study of the number of fecal excretions

Timepoint

Before intervention, 2 weeks after intervention

Method of measurement

Questionnaire

2

Description

frequency of soft stool excretion

Timepoint

Before intervention, 2 weeks after intervention

Method of measurement

Questionnaire

3

Description

examination of the pain score during stool excretion

Timepoint

Before intervention, 2 weeks after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention, 2 weeks after intervention

Method of measurement

Questionnaire

2

Description

Drug Adverse effects

Timepoint

After prescription of drug

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: herbal capsule for 2 weeks and twice daily

Category

Treatment - Drugs

2

Description

Control group: magnesium hydroxide for 2 weeks and twice daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyyatollah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Street address

Mollasadra Ave

City

Tehran

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Postal code

۱۴۳۵۹۱۵۳۷۱

Phone

+98 21 8248 2503

Email

Yunespanahi@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Street address

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Tehran

Postal code

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Email

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yunes Panahi

Position

Clinical pharmacist

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position

Clinical pharmacist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Farnaz heidari

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

clinical study report will be published in the form of an article

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Researchers in the field of health

Under which criteria data/document could be used

If the documentation remains protected

From where data/document is obtainable

Dr.Yunes panahi yunespanahi@bmsu.ac.ir

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

Send an email to the project manager

Comments