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 the 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 hydroxideComparison 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
Province
Tehran
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
Mollasadra Ave
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Phone
+98 21 8248 2503
Email
Yunespanahi@bmsu.ac.ir
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
Street address
Mollasadra Ave
City
Tehran
Province
Tehran
Postal code
۱۴۳۵۹۱۵۳۷۱
Phone
+98 21 8248 2503
Email
Yunespanahi@bmsu.ac.ir

Person responsible for scientific 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
Street address
Mollasadra Ave
City
Tehran

Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 2503
Email
Yunespanahi@bmsu.ac.ir

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
Street address
یخچال
City
Tehran
Province
Tehran
Postal code
194193311
Phone
+98 21 2264 0051
Email
Farnazheidariii@yahoo.com

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