Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of efficacy of flaxeed oil capsule in comparison with olive oil in patients with chronic idiopathic constipation referred to clinic and teachy hospitals of Shahrekord Univercity of Medical Sciences

Protocol summary

Study aim

Determining the effectiveness of flaxseed oil capsule in comparison with olive oil capsule in patients with chronic constipation

Design

Patients randomly assigned to one of three groups A, B, and C. Group C is the control group. In this group, the lifestyle change method is used and explanations are provided them in the form of brochure. In group A (intervention) in addition to lifestyle changes, capsules labeled A and in group B (intervention) ,capsules labeled B are used. Each herbal capsule contains one gram of olive oil or one gram of oil.It is flaxseed (with a completely similar shape) and is prescribed in a daily dose of 5 grams (5 pearls).

Settings and conduct

In this study, the effect of flaxseed oil herbal capsules in the treatment of chronic idiopathic constipation and its comparison with the effect of olive oil herbal capsules in patients referred to Hajar Hospital in Shahrekord and training clinic. The capsules of both intervention groups are similar.The researcher and the patient are not aware of the contents of the capsule. Patients are randomly divided into one of three groups: A (intervention group), B (intervention group) or C (control group).

Participants/Inclusion and exclusion criteria

Entry requirements:Patients in the age group of 25 to 70 years who have had constipation for at least 3 months and the frequency of defecation is a maximum of twice a week. No entry:History of constipation medications (such as calcium channel blockers),Underlying diseases (such as diabetes, hypothyroidism, Parkinson's), pregnancy, drug addiction, history of any type of abdominal surgery, not taking medication as prescribed by a doctor

Intervention groups

Flaxseed oil herbal capsule group and olive oil herbal capsule group

Main outcome variables

Effect on constipation symptoms (stool consistency, number of defication) and effect on fasting blood sugar and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210312050678N1**
Registration date: **2021-03-16, 1399/12/26**
Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**
Update count: **0**

Registration date

2021-03-16, 1399/12/26

Registrant information

Name

Mahnosh Salem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3242 2473

Email address

st-salem.m@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of flaxeed oil capsule in comparison with olive oil in patients with chronic idiopathic constipation referred to clinic and teachy hospitals of Shahrekord Univercity of Medical Sciences

Public title

Evaluation of efficacy of flaxeed oil capsule in comparison with olive oil in patients with chronic idiopathic constipation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 25 to 70 years with a history of chronic idiopathic constipation Patients with constipation for at least 3 months and defecation up to twice a week

Exclusion criteria:

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into one of three groups: A (patient 1 to 35), group B (36 to 70), and group C (71 to 105).

Blinding (investigator's opinion)

Double blinded

Blinding description

In the two intervention groups, drugs with similar appearance and method of use are used.The patient is explained that the herbal capsule contains olive oil or flaxseed oil.The researcher and the patient are not aware of the contents of the capsule and are distinguished by labels A and B.The Data Safety and Monitoring Committee is aware of the contents of each capsule.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Parastar Aven.Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2020-10-20, 1399/07/29

Ethics committee reference number

IR.SKUMS.REC.1399.168

Health conditions studied

1

Description of health condition studied

Chronic idiopathic constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Difficulty of defecation

Timepoint

2 months

Method of measurement

questionnaire

Secondary outcomes

1

Description

Number of bowel movements

Timepoint

2 months

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Group A: Recipient of olive oil herbal capsules.Each capsule contains 1 gram of olive oil. It is recommended to consume 5 grams per day (two before breakfast, two before lunch and one before dinner) for two months.Barij Pharmacy Essential oil is prepared this pearl. Also, lifestyle changes are presented to the patient as a tract.

Category

Treatment - Drugs

2

Description

Intervention group: Group B: Recipient of flaxseed herbal oil capsules.Each capsule contains 1 gram of flaxseed vegetable oil. It is recommended to consume 5 grams per day (two before breakfast, two before lunch and one before dinner) for two months.Barij Pharmacy Essential oil is prepared this pearl. Also, lifestyle changes are presented to the patient as a tract.

Category

Treatment - Drugs

3

Description

Control group: Group C: Lifestyle changes.Necessary recommendations are provided to the patient in the form of tract: do not eat the main meals irregularly and eat them at a specific time. Eat breakfast within an hour after waking up, drink two glasses of warm water on an empty stomach. Consume one and a half Up to liters of water per day (6 to 8 glasses), consumption of 20 to 25 grams of fiber per day (table of high-fiber foods and the amount of fiber per unit of food is provided to patients).

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar Hospital, Shahrekord

Full name of responsible person
Ghorbanali Rahimian

Street address
Parastar Aven

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816754633

Phone
+98 38 3222 0016

Email
mahnoshsalem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Mehraban Sadeghy

Street address
Parastar Aven

City
Shahrekord

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mahnoshsalem@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Mahnosh Salem

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Parastar aven

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mahnosh Salem

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

2022-2023

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments