Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Comparison of the effect of flaxseed powder and magnesium hydroxide syrup on intestinal function of patients with acute myocardial infarction in intensive care units

Protocol summary

Study aim
Determining the effect of flaxseed powder on intestinal function in acute myocardial infarction

Design
A clinical trial with a control group, 70 patients were randomly divided into two groups of 35: flaxseed powder and magnesium hydroxide.

Settings and conduct
Intervention: Three sachets of flaxseed powder, twice a day, for four days, if you have the information and are instructed to show it at 150 and 21 o'clock with 150 cc of water. Control: 20 cc of magnesium hydroxide is consumed once a day at 9 pm, carefully printed in water up to 300 cc, for four days. The study site is Fatemeh Zahra Hospital in Sari.

Participants/Inclusion and exclusion criteria
Include: Confirmation of acute myocardial infarction by a physician, consent to participate in the study, maximum 24 hours after hospitalization, no chronic constipation according to RomeIV , age over 18 years, no history of allergies to herbs, ability to communicate Ophthalmic and verbal, no neurological, thyroid, cerebral, hepatic, renal, cancers, gastrointestinal cancers such as Crohn's, irritable bowel syndrome, intestinal obstruction, ulcers and gastrointestinal bleeding, non-drug addiction, no pregnancy, No EF less than 35%, no participation in other studies at the same time, no antibiotics in the past month, no any laxatives in the last 24 hours

Intervention groups
Intervention: Three sachets of flaxseed powder are given to patients twice a day for four days and they will be taught to drink 150 cc of water at 9 and 21 . Control: Consume 20 cc of magnesium hydroxide syrup once a day at 9 pm, diluted with 300 cc of water, for four days.

Main outcome variables
Intestinal function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N40**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-14, 1400/05/23**
Update count: **0**

Registration date
2021-08-14, 1400/05/23

Registrant information

Name
Masoumeh Bagheri Nesami

Name of organization / entity
Mazandaran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-01, 1400/05/10

Expected recruitment end date
2021-09-01, 1400/06/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of flaxseed powder and magnesium hydroxide syrup on intestinal function of patients with acute myocardial infarction in intensive care units

Public title
The effect of flaxseed powder on intestinal function in patients with acute myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of acute myocardial infarction by a doctor Satisfaction with participation in the study A maximum of 24 hours elapsed from the patient's hospitalization No chronic constipation according to Rome IV criteria Age over 18 years No history of allergies to medicinal plants Ability to communicate visually and verbally No mental illness, thyroid, brain, liver, kidney, cancers, gastrointestinal diseases such as Crohn's, irritable bowel syndrome, intestinal obstruction, ulcers and gastrointestinal bleeding No drug addiction and no pregnancy No ejection fraction (EF) less than 35% Not participating in other studies as usual Do not take antibiotics for the past month Do not consume magnesium hydroxide syrup and any laxatives during the last 24 hours

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
First, patients with inclusion criteria will be selected by available sampling method. Then, using the blocking method, the samples will be assigned to two groups of magnesium hydroxide syrup and flaxseed. The random assignment process will be done with computer software and Randomization Permuted Block method. With this method, 11 blocks of 6 and one block of 4 will be created and samples will be entered based on it. Therefore, 70 opaque and sealed envelopes are designed and based on the information obtained from the computer program, the letters A group of flaxseed powder and group B of magnesium hydroxide are embedded. According to the first patient eligible to open the envelope, the number is executed on it.

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 Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City
Sari

Province
Mazandaran

Postal code
4816715793

Approval date
2021-07-07, 1400/04/16

Ethics committee reference number
IR.MAZUMS.REC.1400.306

Health conditions studied

1

Description of health condition studied
Intestinal function

ICD-10 code
K59

ICD-10 code description
Other functional intestinal disorders

Primary outcomes

1

Description
Intestinal function

Timepoint
Before the intervention and after the intervention

Method of measurement
Bristol stool scale, Intestinal function checklist

2

Description
Digestive disorders

Timepoint
Before the intervention and after the intervention

Method of measurement
Rome IV

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Three sachets of flaxseed powder twice daily, for four days, are given to patients and the patient will be instructed to take all three sachets at 9 am and 9 pm with 150 cc of water.
Category
Treatment - Drugs

2

Description
Control group: Consume 20 cc of magnesium hydroxide syrup once a day at 9 pm, diluted with 300 cc of water, for four days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra Hospital in Sari
Full name of responsible person
Sahar Amjadi Souraki
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Sponsors / Funding sources

1

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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mazandaran 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
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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
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