

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3336 7551

##### Email address

mbagheri@mazums.ac.ir

##### 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

#### Street address

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

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+98 11 3336 1985

#### Email

saharamjadi72@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Mazandaran University of Medical Sciences

#### Full name of responsible person

Dr Majid Saeedi

#### Street address

Mazandaran University of Medical Sciences ,valiye asr highway, Joybar 3way ,Imam Sq,Sari, Mazandaran, Iran

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### Email

mansoorehezati1994@gmail.com

### 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

Mazandaran University of Medical Sciences

#### Full name of responsible person

Masoumeh Bagheri Nesami

#### Position

PhD in Nursing Education

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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**Position**

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Ph.D.

**Other areas of specialty/work**

Nursery

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

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Province**

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**Email**

Anna3043@gmail.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**

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