# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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

**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.
**City**
Sari
**Province**
Mazandaran
**Postal code**
48157-33971
**Phone**
+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
**City**
Sari
**Province**
Mazandaran
**Postal code**
48157-33971
**Phone**
+98 11 3397 8055
**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
**Street address**
Reseach Assistant of Mazandaran University of Medical sciences,Sari, Mazandaran, Iran
**City**
Sari
**Province**
Mazandaran
**Postal code**
4815733971
**Phone**
+98 11 3379 5508
**Email**
mansoorehezaty1994@gmail.com

## Person responsible for scientific 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
**Street address**
Mazandaran University of Medical Sciences,three way Joibar,highway basij,imam square,Sari,Mazandaran
**City**
Sari
**Province**
Mazandaran
**Postal code**
4816715793
**Phone**
+98 11 3379 5508
**Email**
Anna3043@gmail.com

## Person responsible for updating data

**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
**Street address**
Nasibe Nursing and Midwifery Faculty, Sari
**City**
Sari
**Province**
Mazandaran
**Postal code**
4816715793
**Phone**
+98 11 3379 5508
**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