

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of plantago ovata forsk on prevention of constipation among patients with acute myocardial infarction

Protocol summary

Study aim

Determination of the effect of PP on prevention of constipation in patients with acute myocardial infarction

Design

The study is a triangular randomized clinical trial. They were selected by objective sampling method and divided into two intervention and control groups by block method. 110 patients who under the constipation checklist score more than 1 and are exposed The risk is moderate to severe constipation

Settings and conduct

110 of those who are admitted to the ccu section of Amir almomenin and Amir kabir Shahr hospitals in Arak in 1397 and who have the characteristics of the study are studied. A randomized, triangular clinical trials trial. Which is done in two groups. The development of this study is that the patient, the prescribing nurse and the statistician do not know the intervention and control group and the type of intervention.

Participants/Inclusion and exclusion criteria

Acute myocardial infarction, Statement of willingness to participate in the study, Insensitivity to herbal medicines Blood sugar control No chronic constipation Lack of digestive diseases No use of constipation drugs Unlimited fluid intake Being hospitalized for at least 3 days Motionless on the bed Earn score 1 and more based on constipation tool Pregnancy and lactation

Intervention groups

The intervention group receives a 5-gram pre-filled flour powder prepared by a researcher, fasting for 3 days a day. The powder should be in 150-210 ml of hot water for 1-5 hours before use. Soak up. The placebo control group will receive the saccharide, such as the intervention group but breadcrumbs.

Main outcome variables

Constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040439N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Zahra Asgarynezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 8179

Email address

z.asgarinezhad@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of plantago ovata forsk on prevention of constipation among patients with acute myocardial infarction

Public title

Effect of plantago ovata forsk on prevention of constipation among patients with acute myocardial infarction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patient willingness to participate in the study no reaction to herbal productions no chronic constipation

Exclusion criteria:

diabetic patients

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

convenience sampling and blocking method

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is unaware of the type of herbal medicine used to prevent constipation, because both medicine and placebo are saccharified in volatile water and consumed. On the other hand, the data collection nurse is not aware of the patient's drug use, as the researcher gave the patient with a herbal drug with the help of a nurse co-worker before data collection. The statistician is also unaware of the two groups because the data is presented in the form of the intervention group code and the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Niayesh Apartment, Behdary St, Nurse Sq

City

Arak

Province

Markazi

Postal code

3819684764

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.ARAKMU.REC.1397.060

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

121

ICD-10 code description

121

Primary outcomes

1

Description

Constipation

Timepoint

For three consecutive days

Method of measurement

Constipation Assessment Scale

Secondary outcomes

1

Description

dose not have

Timepoint

dose not have

Method of measurement

dose not have

Intervention groups

1

Description

Intervention group: The intervention group after receiving the terms of participation in the study for a period of three consecutive days receive the PSF in a fasting state.

Category

Treatment - Drugs

2

Description

Control group: The group receives the placebo-based ruskus for three consecutive days and fasting.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir Hospital

Full name of responsible person

Zahra Asgarynezhad

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Web page address

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Recruitment center

Name of recruitment center

Amir almomenin Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmandzadeghan

Street address

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Zahra Asgarynezhad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Arak University of Medical Sciences

Full name of responsible person

Zahra Asgarynezhad

Position

Student

Latest degree

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Other areas of specialty/work