

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of acupressure on the intestinal function of patients with acute myocardial infarction under primary angioplasty

Protocol summary

Study aim

The determine of effects of acupressure on intestinal function of patients with acute myocardial infarction

Design

Three-group randomized controlled clinical trial

Settings and conduct

The SJ6 - LI4 - ST25- SP6 points of both members are determined symmetrically by the researcher's fingers. Acupressure will be performed twice a day (10am and 6pm) from the beginning of the day for three days.

Participants/Inclusion and exclusion criteria

Acute myocardial infarction, which is confirmed by a laboratory positive blood troponin level and confirmed by a physician. No more than 12 hours of myocardial infarction No chronic constipation based on RomelV criteria Written and verbal consent to participate in the study Age above 18 Ability to communicate verbally No known mental illness under treatment Absence of ulcers, organ failure, tenderness and fractures in acupressure points Lack of simultaneous participation in other intervention studies no thyroid disease, incurable, neuromuscular, congenital gastrointestinal malformations and renal failure, no gastrointestinal disorders (gastric ulcer, chronic constipation history, fisher, hemorrhoids, prolapse of the rectum, obstruction of the rectum, obstruction) , Biography and physical examination by a physician No dependence or addiction to any drugs

Intervention groups

The SJ6 - LI4 - ST25- SP6 points of both members are determined symmetrically by the researcher's fingers. Acupressure will be performed twice daily (10am and 6pm) from the beginning of the day for three days. Control group: These patients are given nutritional and routine heart disease training. . There is no intervention in this group. Sham group: The sham group offers routine nursing nutrition and care training

Main outcome variables

Improve intestinal function and prevent constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110906007494N31**

Registration date: **2020-03-20, 1399/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-20, 1399/01/01**

Update count: **0**

Registration date

2020-03-20, 1399/01/01

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure on the intestinal function of patients with acute myocardial infarction under primary angioplasty

Public title

acupressure in cardiac patient

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Acute myocardial infarction, which is confirmed by a laboratory positive blood troponin level and confirmed by a physician. Written and verbal consent to participate in the study Age over 18 Ability to communicate verbally

Exclusion criteria:

No more than 12 hours of myocardial infarction No chronic constipation based on RomeIV criteria Lack of known mental illnesses under treatment Absence of ulcers, organ failure, tenderness and fractures in acupressure points Lack of simultaneous participation in other intervention studies no thyroid disease, incurable, neuromuscular, congenital gastrointestinal malformations and renal failure, no gastrointestinal disorders (gastric ulcer, chronic constipation history, fisher, hemorrhoids, prolapse of the rectum, obstruction of the rectum, obstruction) , Biography and physical examination by a physician No dependence or addiction to any drug

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients were randomly assigned to three groups of 30 acupressure, sham, and control groups using random numbers provided with computer software and Randomization Permuted Block. 15 to 6 blocks so that there are 2 people in each block. Therefore, 90 envelopes are designed and embedded inside based on information obtained from the computer program of letters A of acupressure group, B of sham group and C of control group. Based on the patient's admission date, the priority of opening the envelope is executed on the order of the number.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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

2020-01-04, 1398/10/14

Ethics committee reference number

IR.MAZUMS.REC.1398.1256

Health conditions studied

1

Description of health condition studied

myocardial infarction

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

intestinal function

Timepoint

Before and the first day to 4th day of intervention

Method of measurement

Bristol scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1 : The SJ6 - LI4 - ST25- SP6 points of both members are determined symmetrically by the researcher's fingers. Acupressure will be performed twice

daily (10 am and 6 pm) from the beginning of the day for three days. Point ST25 (Tianshu) is located two fingers away from the navel . The LI4 (Hegu) point lies at the depth of the muscle bundle, resulting from the thumb and forefinger . The SJ6 (Zhigou) dot is located four inches above the transverse line of the wrist between Radius and Ulna . The SP6 (sanyinjiao) point is four fingers above the medial ankle behind the posterior edge of the tibia. Apply acupressure on each spot symmetrically for two minutes. Apply a minute with your thumb pressed vertically, then rest for 5 seconds and then rotate for one minute. A total of 9 minutes of intervention will be administered to the patient each time. Nutrition training and routine nursing care are also provided.

Category

Prevention

2

Description

Intervention group2: The sham group offers routine nursing education and care, and the procedure will be exactly the same as the intervention group, except that pressure is close to the acupressure points according to accredited acupressure specialists in the field, which is about half that. No special timber is applied. The order of the pressure, the type of pressure, the position of the patient, the time and the amount of pressure in the test and sham groups will be the same. The location of the pressure points is similar to that of the intervention group except that they are 1.5 cm apart. It should be noted that in both groups, the pressure procedure will be taught by one person (the researcher). Intestinal function and checklists will then be completed before the intervention and in the first to fourth days.

Category

Placebo

3

Description

Control group: After introducing and expressing the aims of the study and obtaining written informed consent and patient's consent to participate in the study, these patients receive nutritional and routine heart disease training. The demographic and medical information questionnaire, symptom checklist, Rome scale and Bristol are completed. There is no intervention in this group. Intestinal function indicators will be completed before the intervention and in the first to fourth days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran Heart Center

Full name of responsible person

Mahsa Kamali

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research 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

2

Sponsor

Name of organization / entity

University researches Assistance

Full name of responsible person

Dr Masoomeh Bagheri Nesami

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

Yes

Title of funding source

University researches Assistance

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

Dr. Masoomeh Bagheri Nasami

Position

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

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Latest degree

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Other areas of specialty/work

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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

No decision yet

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