

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Foot Reflexology on Comfort And Physiological indices in Patients with Acute Coronary Syndrome

Protocol summary

Study aim

The effect of foot reflexology on comfort and physiological parameters in patients with acute coronary syndrome

Design

Patients randomly assigned to the intervention and control groups (68 patients each) Will be allocated. In group 1 (intervention group) patients will have reflexology once. The session will last 30 minutes for each leg for 15 minutes. In the control group, patients do not receive any intervention from the researcher, and for the same interventions, the foot is touched once for 30 minutes without pressing each leg for 15 minutes.

Settings and conduct

In group 1 (intervention group) patients will have reflexology once. The session will last 30 minutes for each leg for 15 minutes. In the control group, patients do not receive any intervention from the researcher, and for the same interventions, the foot is touched once for 30 minutes without pressing each leg for 15 minutes. The project will be implemented in Amir Kabir and Amiyalmomenin hospitals in Arak. The design is double-sided blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Willingness to participate in the study 2. Patients diagnosed with acute coronary syndrome by a specialist cardiologist 3. Age between 18 and 65 years 4. No other non-pharmacological relaxation interventions 5. Absence of scars on the legs Exclusion criteria: 1. Unwillingness to continue participating in the study 2. Wounds in the legs 3. Patient's death

Intervention groups

In group 1 (intervention group) patients will have reflexology once. The session will last 30 minutes for each leg for 15 minutes. In the control group, patients do not receive any intervention from the researcher.

Main outcome variables

1. Comfort 2. Physiological Indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180519039711N3**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Mohamad Golitaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

m.golitaleb@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-29, 1398/11/09

Expected recruitment end date

2020-05-29, 1399/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Foot Reflexology on Comfort And Physiological indices in Patients with Acute Coronary Syndrome

Public title

The effect of reflexology on comfort and physiological parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients with Acute Coronary Syndrome Admitted to Cardiac Care Unit 2. Willingness to participate in the study 3. Patients with a diagnosis Acute coronary syndrome by a cardiologist 4. Age between 18 and 65 years 5. No other non-pharmacological relaxation interventions 6. Absence of scars on the legs

Exclusion criteria:

1. Unwillingness to continue participating in the study 2. Wounds in the legs 3. Patient's death

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, 17 blocks of 8 different letters of T and C are created (which represent the intervention and control groups). 68 individuals belong to the intervention group and 68 individuals belong to the control group. These blocks were then randomly selected to obtain a combination of 136 blocks, respectively. The resulting combination of letters is placed individually in 136 envelopes and each envelope is opened in order to determine which group the patient falls into.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, clinical caregivers, and data analysts are not aware of the patients assigned to the intervention or control group.

Placebo

Not 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

Vice-Chancellor of Education and Research Arak University of Medical Sciences., Basij Square, Arak, Iran

City

Arak

Province

Markazi

Postal code

7558538149

Approval date

2019-12-13, 1398/09/22

Ethics committee reference number

IR.ARAKMU.REC.1398.238

Health conditions studied

1

Description of health condition studied

Acute coronary syndrom

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Heart rate

Timepoint

Before and after intervention

Method of measurement

Heart rate (beats/min) will be measured with cardiac monitor

2

Description

Systolic pressure

Timepoint

Before and after intervention

Method of measurement

Systolic pressure (mmhg) will be measured with cardiac monitor

3

Description

Diastolic pressure

Timepoint

Before and after intervention

Method of measurement

Diastolic pressure (mmhg) will be measured with cardiac monitor

4

Description

Arterial Oxygen Saturation Percentage

Timepoint

Before and after intervention

Method of measurement

Pulse Oximeter

Secondary outcomes

1

Description

Comfort

Timepoint

Before and after intervention

Method of measurement

Kulkaba Convenience Questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: In group 1 (intervention group), patients will have reflexology once. The session will last 30 minutes for each leg for 15 minutes.

Category

N/A

2

Description

Control group: In the control group, patients do not receive any intervention from the researcher, and for the same interventions, the foot is touched once for 30 minutes without pressing each leg for 15 minutes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Mohamad Golitaleb

Street address

Basij square. Arak

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2

Recruitment center

Name of recruitment center

Amir Kabir Hospital

Full name of responsible person

Mohamad Golitaleb

Street address

Amir Kabir Hospital .Nursing Square - Shiroudi Street .Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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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

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

Mahtab Farahani

Position

Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Full name of responsible person

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Position

Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

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Web page address<http://arakmu.ac.ir/>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/documentAll information and results will be mentioned in the final
report and article.**When the data will become available and for how long**All information and results will be mentioned in the final
report and article.**To whom data/document is available****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mohamad Golitaleb

Position

Academic instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Markazi

All information and results will be mentioned in the final report and article.

Under which criteria data/document could be used

All information and results will be mentioned in the final report and article.

From where data/document is obtainable

All information and results will be mentioned in the final report and article.

What processes are involved for a request to access data/document

All information and results will be mentioned in the final report and article.

Comments

All information and results will be mentioned in the final report and article.