Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The reflexive effect of rubbing the palm of the foot palm (reflexology) on chest pain, anxiety, sleep quality, fatigue and physiological parameters in patients with acute myocardial infarction followed by treatment with Streptokinase.

Protocol summary

Summary

The aim of study is to determine the reflexive effect of rubbing the palm of the foot palm (reflexology) on chest pain, anxiety, sleep quality, fatigue and physiological parameters in patients with acute myocardial infarction followed by treatment with Streptokinase. Inclusion criteria: patient consent for participation in the study, acute myocardial infarction for the first time, treatment with Streptokinase, no history for the use of reflexology. Exclusion criteria: vision and hearing disorders, history of chronic pains, addiction to alcohol, or Opioids, leg fracture, sensory disorder, wound infecton in legs, skin diseases, graft, vascular disorders in legs, amputation in lower extremities, sensitivity to touch or massage, intolerance for intervention, any acute condition at the time of intervention, history of cardiopulmonary resuscitation; leg edema and keratosis. Population under study: patients with acute myocardial infarction hospitalized in coronary care unit in the Rajaei hospital in Karaj. Sample size: A pilot study including15 patients from each group, will determine the size of the sample. First intervention: Foot palm reflexology at the heart of the left foot (ball center of foot) is performed for 20-minutes. Second intervention: Foot palm reflexology on the right foot, the heel (the abdomen and pelvis area) is performed for 20-minute. Third intervention: No intervention. the researcher would be present by patient's side in the whole duration of experiment. Chest pain intensity, anxiety, fatigue and physiological parameters will be recorded before, immediately and 20 minutes after interventions. This intervention is being done for three consecutive days and the intensty will be assessed. The Quality of sleep will be recorded before and day 4th of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501166318N4**
Registration date: **2015-03-14, 1393/12/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

Name

Monir Nobahar

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The reflexive effect of rubbing the palm of the foot palm (reflexology) on chest pain, anxiety, sleep quality, fatigue and physiological parameters in patients with acute myocardial infarction followed by treatment with Streptokinase.

Public title
The reflexive effect of rubbing the palm of the foot palm (reflexology) on chest pain, anxiety, sleep quality, fatigue and physiological parameters in patients with acute myocardial infarction followed by treatment with Streptokinase.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: patient consent for participation in the study, acute myocardial infarction for the first time, treatment with Streptokinase, no history for the use of reflexology. Exclusion criteria: vision and hearing disorders, history of chronic pains, addiction to alcohol, or Opioids, leg fracture, sensory disorder, wound infecton in legs, skin diseases, graft, vascular disorders in legs, amputation in lower extremities, sensitivity to touch or massage, intolerance for intervention, any acute condition at the time of intervention, history of cardiopulmonary resuscitation; leg edema and keratosis.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
Semnan, University of Medical Sciences,Nursing and Paramedical Faculty

City
Semnan

Postal code
3513138111

Approval date
2015-02-12, 1393/11/23

Ethics committee reference number
93/551666

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction

ICD-10 code
I21.9

ICD-10 code description
Acute myocardial infarction, unspecified

Primary outcomes

1

Description
Chest pain intensity

Timepoint
Before and immediately after and 20 minutes after the intervention

Method of measurement
Chest pain intensity will be recorded before, immediately and 20 minutes after intervention. This intervention is being performed for three consecutive days and the intensities will be assessed. Information for each person will be recorded in form of questionnaire specfic for each patient. Visual analogue scale will be used for chest pain assessment.

2

Description
Fatigue

Timepoint
Before and immediately after and 20 minutes after the intervention

Method of measurement
Fatigue will be measured and recorded before, immediately and 20 minutes after the intervention. This intervention is being performed for three consecutive days and the intensities will be assessed. Information for each person will be recorded in form of questionnaire specific for each patient. Visual analogue scale will be used for chest pain assessment.

3

Description
Anxiety

Timepoint
Before and immediately after and 20 minutes after the intervention
Method of measurement
Anxiety will be measured and recorded before, immediately and 20 minutes after the intervention. This intervention is being performed for three consecutive days and the intensities will be assessed. Information for each person will be recorded in form of questionnaire specfic for each patient. Visual analogue scale will be used for chest pain assessment.

4

Description
Physiological parameters
Timepoint
Before and immediately after and 20 minutes after the intervention
Method of measurement
Physiological parameters will be measured and recorded before, immediately and 20 minutes after the intervention. This intervention is being performed for three consecutive days and the intensities will be assessed. Information for each person will be recorded in form of questionnaire specific for each patient. The record of physiological parameters include ;blood pressure, pulse, respiration, temperature, blood oxygen saturation and cardiac rhythm (to determine the number of PVC and PAC).

5

Description
Quality of sleep
Timepoint
before intervention and the day4th
Method of measurement
The Quality of sleep will be measured and recorded before the intervention and on the day 4th. The Pittsburgh questionnaire will be used for assessing the quality of sleep. Information for each person will be recorded in a specfic questionnaire for each patient.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1: The masseur keeps the curtains closed around the patient and minimizes the external noises. It is requested from the patient to lie down on the bed and his foot is washed with warm water, then a pillow is placed under his knee to relax the lower limbs. Talking to the patient is not allowed during the massage. Masseur must remove his ring, clock and jewelry and wash his hands. Then he sits on the chair at the end of the patient’s bed in a comfortable position and lubricates patient's left foot for one minute by using lubricanting cream (lubricant cream is the healthy brand of transparent and water soluble product, without salt, alcohol, and essence. it will do not create sensitivity and allergic reactions, and hasn't therapeutic value) and then for 20-minute foot reflexology massage in the heart of the left foot (ball center of foot) will be performed.
Category
Treatment - Other

2

Description
Intervention 2: The masseur keeps the curtains closed around the patient and minimizes the external noises. It is requested from the patient to lie down on the bed and his foot is washed with warm water, then a pillow is placed under his knee to relax the lower limb. Talking to the patient is not allowed during the massage. Masseur must remove his ring, clock and jewelry and wash his hands. Then he sits on the chair at the end of the patient’s bed in a comfortable position and lubricates patient's left foot for one minute by using lubricanting cream (lubricant cream is the healthy brand of transparent and water soluble product, without salt, alcohol, and essence. it will do not create sensitivity and allergic reactions, and hasn't therapeutic value) and then for 20-minute foot reflexology massage in the heart of the right foot, the heel (the abdomen and pelvis area) will be performed.
Category
Other

3

Description
Intervention 3: No intervention, the researcher will be present by the patient’s side in the whole duration of 20 minutes.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Karaj Rajaei Hospital
Full name of responsible person
Monir Nobahar
Street address
Semnan University of Medical Sciences
City
Semnan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr. Ali Rashidypour
Street address
Semnan University of Medical Sciences, Boulvar Basij, Semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty