

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of left sole massage on pain relief and hemodynamic condition of patients with chest pain in Ardabil

Protocol summary

Summary

Introduction: Chest pain is some pressure, ache, and burning or stabbing sensation in the chest whose reflexology is most commonly performed on the feet. Pitchfork of left sole is the cardiac reflex point. The aim of this study was to determine the effect of left sole massage on hemodynamic condition and pain relief in patients with chest pain. Methods: This clinical trial study was conducted on 180 patients with chest pain admitted to Imam Khomeini hospital's emergency room in Ardabil. McGill visual pain scale was used to measure pain intensity and left sole massage determined for all eviating pain was evaluated in two steps. Level of significance was considered $P < 0.05$ in all of these tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503244256N5**

Registration date: **2015-04-20, 1394/01/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-20, 1394/01/31

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of left sole massage on pain relief and hemodynamic condition of patients with chest pain in Ardabil

Public title

Effect of left sole massage on pain relief and hemodynamic condition of patients with chest pain in Ardabil

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age below 70 years old; history of diabetes less than 15 years; no addiction; healthy feet; full consciousness, and absence of mental problems. exclusion criteria. Patients who, prior to their consultation for chest pain, had been diagnosed for having coronary insufficiency by physiological methods or had had an acute myocardial infarction or had been the subject of coronary revascularization during the previous year, were excluded.

Age

From **30 years** old

Gender

Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: 180
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

<u>1</u>
Ethics committee
Name of ethics committee
Ardabil University of Medical Sciences
Street address
Ardabil University of Medical Sciences, Ardabil, Iran.
City
Ardabil
Postal code
Approval date
2014-07-27, 1393/05/05
Ethics committee reference number
9114

Health conditions studied

<u>1</u>
Description of health condition studied
Ischemic heart disease
ICD-10 code
I20-I25
ICD-10 code description
Ischemic heart disease

Primary outcomes

<u>1</u>
Description
Chest pain
Timepoint
Before and after intervention
Method of measurement
Visual analogue scale

Secondary outcomes

<u>1</u>
Description
Pain and hemodynamic conditions
Timepoint
Before and after intervention
Method of measurement
Visual analogue scale and monitoring

Intervention groups

<u>1</u>
Description
In the massage group, a trained and experienced nurse in this field, massaged left sole of the patients in metatarsals of 2, 3& 4 (adductor hallucis) for 15 minutes. The massage intervention included light/gentle effleurage; petrissage and myofascial trigger point release. The massager washed hands with warm water and pressed the point with her both thumbs without any pause. Then, the patient was asked about the pain intensity and data was recorded. The vital signs were also measured and documented.
Category
Treatment - Devices

<u>2</u>
Description
In the placebo group, the patients received instead of the reflexology foot massage, an uncertain point on the right foot was massaged. Then 15 min, without any intervention, just checked patients as a wash out period.
Category
Treatment - Drugs

Recruitment centers

<u>1</u>
Recruitment center
Name of recruitment center
Emam Khomeini hospital of Ardabil
Full name of responsible person
Nasrin Samadi
Street address
Emam Khomeini hospital, Ardabil
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Sponsors / Funding sources

<u>1</u>
Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person

Dr. Habibzade
Street address
 Ardabil University of Medical Sciences, Ardabil, Iran.
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 Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Ardabil 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

Contact
Name of organization / entity
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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