

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of acupressure on the severity of low back pain and fatigue after coronary atrial angioplasty by femoral

Protocol summary

Study aim

Determining the effect of acupressure on the severity of low back pain and fatigue in patients after coronary angioplasty through the femoral artery

Design

Randomized controlled clinical trial available in 3 groups of intervention, false intervention, and control on 75 patients using a pack of 75

Settings and conduct

Random and available sampling in Fatemeh Zahra Hospital in Sari

Participants/Inclusion and exclusion criteria

Inclusion criteria include informed consent, age over 18 years, maximum time of femoral angioplasty in lip coat 1 hour, stabilization of vital signs, no communication problems, taking soft pills before angioplasty, no scars, lesions, scratches or abnormalities Acupuncture points skin. Exclusion criteria include arrhythmia and complications after angioplasty, critical condition of the patient and the patient returning to the lip coat, use of narcotic drugs and other analgesics, Existence of motor and neuromuscular disorders such as Parkinson's, Multiple Sclerosis, Congenital lumbar spine disorders, Lumbar related diseases including lumbar disc herniation with evidence of pain in the legs, Spinal canal stenosis, Lumbar surgery, Severe low back pain due to discopathy In the last 1 month, see a specialist at least once due to back pain or severe back pain in the last 1 month

Intervention groups

Acupressure in the experimental group for 14 minutes at 2, 4, 6 and 8 hours after angioplasty Massage in the control group for 14 minutes at 2, 4, 6 and 8 hours after angioplasty

Main outcome variables

Severity of low back pain and fatigue after angioplasty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024342N7**
Registration date: **2021-01-07, 1399/10/18**
Registration timing: **prospective**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Vida Shafipour

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2021-01-29, 1399/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure on the severity of low back pain and fatigue after coronary atrial angioplasty by

femoral

Public title

The effect of acupressure on low back pain and fatigue

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Obtaining informed consent from the patient Age over 18 years Maximum time of femoral angioplasty in lip coat 1 hour Stabilization of vital signs including blood pressure, temperature, pulse, respiration No communication problems such as hearing or speech impairment Taking oral sedatives according to the routine of the relevant unit before angioplasty No scars, lesions, scratches or abnormalities on the skin of acupressure points

Exclusion criteria:

1. hemodynamic symptoms (blood pressure, pulse, respiration) 2. Arrhythmia and complications after angioplasty (bleeding, hematoma) 3. Critical condition of the patient and return of the patient to the lip coat 4. Use of narcotic drugs and other analgesics 5. Existence of motor and neuromuscular disorders such as Parkinson's, multiple sclerosis, congenital lumbar vertebral disorders Lumbar-related diseases include lumbar disc herniation with evidence of referred pain in the legs, spinal canal stenosis, lumbar surgery, severe low back pain due to discopathy in the last 1 month, see a specialist at least once due to back pain or back pain Intense in the last 1 month

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized controlled clinical trial is available. Thus, 25 people in the acupressure group, 25 people in the false intervention group and 25 people in the control group will be selected for research. 75 envelopes are provided and number one to 75 is written on each envelope. And is placed in the envelope of group A, group B and group C. Eligible patients will receive the envelopes in order, and if it was group A, it will be in the intervention group, if it was group B, it will be in the second intervention group, and if it was group C, it will be in the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not 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

Iran, Mazandaran, Sari, Moallem Square, University Building No. 2, Vice Chancellor for Research, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2020-07-25, 1399/05/04

Ethics committee reference number

IR.MAZUMS.REC.1399.486

Health conditions studied**1****Description of health condition studied**

Angioplasty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fatigue after angioplasty

Timepoint

At 2, 4, 6 and 8 hours after angioplasty

Method of measurement

Visual Analogue fatigue Scale(vafs)

2**Description**

Low back pain after angioplasty

Timepoint

At 2, 4, 6 and 8 hours after angioplasty

Method of measurement

Visual Analogue Scale(vas)

Secondary outcomes

empty

Intervention groups

1

Description

In the acupuncture intervention group in four areas: point 36 of the stomach (ST36), submandibular midline (GV26), point 3 of the small intestine (SI3), point 60 of the bladder (BL60) each for two minutes for a total of fourteen minutes at intervals of two, Four, six and eight hours after the angioplasty is performed, then the low back pain and fatigue questionnaire is completed between two, four, six and eight hours before and after the acupuncture intervention by the patient.

Category

Treatment - Other

2

Description

In the control group, the false intervention was performed as a gentle massage in four points: ST36, GV26, SI3, BL60, for two minutes each for a total of fourteen minutes at intervals of two, four, six and eight hours after angioplasty. The interval of two, four, six and eight hours before and after the gentle massage is completed by the patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital in Sari

Full name of responsible person

Vida Shafipour

Street address

Iran, Sari, School of Nursing and Midwifery,
Mazandaran University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

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Iran, Mazandaran, Sari, Moallem Square, Moallem
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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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Vida Shafipour

Position

PhD, faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific

inquiries

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Name of organization / entity

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Position

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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)

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