Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Vida Shafipour

Name of organization / entity
Mazandaran University of Medical Sciences

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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 acupressure 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 acupressure 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 Street, Vice Chancellor for Research

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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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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