

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of Foot Reflexology and Auriculotherapy on Low Back Pain after Coronary Angiography

Protocol summary

Study aim

Comparison of the Effect of Foot Reflexology and Auriculotherapy on Low Back Pain after Coronary Angiography

Design

Clinical trials, three parallel group ,randomised

Settings and conduct

This study is a randomized clinical trial In the post-angiography ward of Razi Hospital of Birjand in 1397 in patients that will be under angiography, Samples will be selected on available sampling that have entry criteria. Written informed consent, information form Demographics will be complete. After performing angiography VAS criteria for patients will be complete. Patients will be randomly assigned to three groups of control, foot reflexology intervention, and auriculotherapy intervention, by permutation blocking. Interventions will be performed for patients. Immediately after the intervention, as well as at 2, 4, and 6 hours after intervention, the VAS criteria for patients in three groups will be completed again. At the end of the data, descriptive and inferential statistics will be analyzed and analyzed

Participants/Inclusion and exclusion criteria

Satisfaction - Angiography from femoral artery - health foot in the reflexology group and health in ear in auriculotherapy group

Intervention groups

Control, Foot Reflexology, auriculotherapy

Main outcome variables

A) In the reflexology ,two minutes of general massage, one minute of rest, two minutes of massaging the solar plexus and the spine, a minute of rest, two minutes of massage on the spinal column. A total of 8 minutes of foot massage will be performed on feet and 16 minutes in two legs. B) In auriculotherapy group, massages applied by a grainy object in Shenmen points, the Lumbo sacral point and the kidneys point for 2 minutes with a 1 minute rest each ear will take 8 minutes (16 minutes for

two ears). c) The routine care team will be performed in control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190203042606N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

Mojgan Kardan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3221 7160

Email address

mo.kardan54@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Foot Reflexology and Auriculotherapy on Low Back Pain after Coronary Angiography

Public title

Effect of Foot Reflexology and Auriculotherapy on Low Back Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having written consent to participate in the study having age of 60-30 years performing Angiography by femoral artery and using the femoral artery just from the right side having a health feet in the reflexology group and health ear in the Auriculotherapy group having complete consciousness normal Touching the lower pulses of the catheter entrance site Having the mental capability of the company in the study and the ability to collaborate in the study not having back pain from a week before the angiography no known bleeding disorder (such as platelets below 75,000 per cc, 90 seconds <PTT) Lack of sensory impairment related to back pain(for example, paraplegia) or sensory impairment foot and ears no history of hernia of the patient's wrists or backbone surgery no thrombosis, phlebitis, gallstones or kidney stones, fever or infectious disease no drug use, sedation within 4 hours before or after angiography The patient's sleeping status after angiography is supine without head elevate

Exclusion criteria:

Any complication or unstable condition during or after angiography such as active bleeding from the catheter, causing disrhythmia or hypertension above 190/110 mmHg Pain in the first completed VAS after angiography

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **174**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly by permutation blocking method: There are 20 modes for selecting three groups, for example (abc, acb, bca, bac). Each time, a mode will be selected and this will continue until the completion of the samples.

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 Birjand University of Medical Sciences

Street address

No40, Bahman1, Ghaffary Street

City

Birjand

Province

South Khorasan

Postal code

9718897188

Approval date

2019-01-14, 1397/10/24

Ethics committee reference number

ir.bums.rec.1397.289

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

LowBack Pain after Coronary Angiography

ICD-10 code

(I20-I25)

ICD-10 code description

Ischaemic heart diseases

Primary outcomes**1****Description**

LowBack Pain after Coronary Angiography

Timepoint

The mean of back pain score before intervention, immediately after intervention and at 2, 4 and 6 hours after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

LowBack Pain after Coronary Angiography

Timepoint

The mean of back pain score before intervention, immediately after

Method of measurement

Visual Analogue Scale

Intervention groups**1****Description**

Intervention group:1 Foot Reflexology

Category

Treatment - Other

2**Description**

Intervention group: 2Auriculotherapy

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi hospital In Birjand

Full name of responsible person

Mojgan Kardan

Street address

Razi Hospital, Ghafari St

City

Birjand

Province

South Khorasan

Postal code

9717844471

Phone

+98 56 3162 6000

Fax

+98 56 3238 1128

Email

razihospital@bums.ac.ir

Web page address

http://msit.bums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

Street address

Ghafari St, Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717843577

Phone

+98 56 3239 5000

Fax

+98 56 3243 0076

Email

public_r@bums.ac.ir

Web page address

http://msit.bums.ac.ir/

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Mojgan Kardan

Position

post graduate Student, Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No40,bahman1,gafary street

City

Birjand

Province

South Khorasan

Postal code

9718897188

Phone

+98 32217160

Email

mo.kardan54@gmail.com

Web page address

http://msit.bums.ac.ir/

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Mojgan

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Web page address

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mojgan Kardan

Position

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Individual unknown individuals will be shared, such as age, gender, and body mass index.

When the data will become available and for how long

The start of the access period will be 12 months after the publication of the results. Data will be available for one year

To whom data/document is available

Data will be available to researchers working in University and academia.

Under which criteria data/document could be used

Data / Documentation will be used to help design similar studies. If requested, researchers will be provided with logical data / documentary reasons.

From where data/document is obtainable

Researchers can contact the author with mo.kardan54@gmail.com email address

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

Researchers will receive data / documentation within a month by presenting their study objectives and the type of data / document application they apply and sending their email.

Comments