Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
۹۷۱۷۸۴۴۴۷۱
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
۹۷۱۷۸۵۳۵۷۷
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
Post graduate Student, Surgical Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No40, Bahman1, Ghaffary Street

City
Birjand

Province
South Khorasan

Postal code
9718897188

Phone
+98 56 3221 7160

Email
mo.kardan54@gmail.com

Web page address
http://msit.bums.ac.ir/

Person responsible for updating data

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, Ghaffary Street

City
Birjand

Province
South Khorasan

Postal code
9718897188

Phone
+98 56 3221 7160

Email
mo.kardan54@gmail.com

Web page address
http://msit.bums.ac.ir/

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 yea

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 adress

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