Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effect of Basilic vein FASD(Blood letting) with Acupuncture and Physiotherapy on pain and disability of patients with chronic low back pain

Protocol summary

Study aim
Determining the effect of Basilic vein FASD(phlebotomy), acupuncture and physiotherapy on pain and disability caused by chronic low back pain Comparing the effect of FASD, acupuncture and physiotherapy on pain and disability caused by chronic low back pain

Design
Non-randomized clinical trial with 3 parallel groups, on 90 patients and with 1 month follow-up of patients

Settings and conduct
Basilic vein FASD(venisection) will be performed 2 times and 2 weeks apart. The bistoury blade used is number 11, the gap created is 2 to 5 millimeters, and the amount of blood taken is about 50 to 100 cc (in Ahmadieh Health Center). Acupuncture will be performed in 10 sessions(3 sessions per week). Each treatment session lasts about 20 minutes. Acupuncture is performed with electrical stimulation (electroacupuncture). In addition to the local points, the other points selected based on the references will be: DU4, UB23, UB40, Ki3, DU20 The needles used will be 0.25 × 40 in size (in Heravi Health Center). Patients in the physiotherapy group undergo regular sessions of 10 sessions to perform standard physiotherapy for chronic low back pain.(in Imam Khomeini Hospital).

Participants/Inclusion and exclusion criteria
Inclusion criteria :Chronic nonspecific mechanical low back pain A history of more than three months of low back pain Age range between 30 and 70 years Exclusion criteria:Surgical history due to low back pain

Intervention groups
Fasd Group:Right Basilic vein FASD 2 times with an interval of 2 weeks. Acupuncture group: in 10 sessions by electroacupuncture method in defined points Physiotherapy group:10 sessions of standard physiotherapy for chronic low back pain. Patients in all three groups will be trained in lifestyle and exercise to improve pain.

Main outcome variables
The severity of pain and disability in Oswestry questionnaire Pain intensity score in VAS (Visual Analogue Scale) questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200425047197N1**
Registration date: **2020-05-28, 1399/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-28, 1399/03/08**
Update count: **0**

Registration date
2020-05-28, 1399/03/08

Registrant information

Name
Moein Jamali

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8897 6530

Email address
jamali-m@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-25, 1399/03/05

Expected recruitment end date
2021-08-27, 1400/06/05

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of Basilic vein FASD(Blood letting) with Acupuncture and Physiotherapy on pain and disability of patients with chronic low back pain

Public title
Comparing the effect of FASD,Acupuncture and physiotherapy on low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Personal and conscious consent of the individual to participate in the research project Chronic mechanical low back pain without any specific pathology such as inflammation of the nerve root, spinal stenosis, spondylolysis, spondylolisthesis, vertebral fracture A history of more than three months of pain Confirmation of chronic low back pain and clinical examination by a specialist to rule out any pathology Age range between 30 and 70 years
Exclusion criteria:
Pregnancy or lactation Surgical history due to low back pain Non-mechanical back pain (wakes the patient up at night or causes pain and dryness in the morning) History of trauma, especially in the elderly Fever, sweating and weight loss without justification in recent months Long-term treatment with corticosteroeids Symptoms of cauda aquina syndrome include numbness and weakness in both legs, anal pain, perineal numbness or paresthesia, sphincter paralysis. Ankylosing spondylitis and inflammatory rheumatoid arthritis Existence of neuropathy or neurological problems during the examination Severe untreated scoliosis Infection at the site or spinal cord Acute radiculopathy (active herniated disc) Psychopathic disorders Uncontrolled diabetes or high blood pressure Participatory low back pain such as uterine or gastrointestinal involvement such as IBD Consumption of digoxin, warfarin, heparin Drug addiction, sedatives, alcohol, etc. Injecting anesthetics or corticosteroids for up to 4 weeks before starting treatment Fainting history after FASD or Hijamat(wet cupping)
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Iran National Committee for Ethics in Biomedical Research
Street address
No. 27, Sarparast St, West Taleghani Ave, Felestin Sq
City
Tehran
Province
Tehran
Postal code
1416663361
Approval date
2020-04-11, 1399/01/23
Ethics committee reference number
IR.TUMS.VCR.REC.1399.202

Health conditions studied

1

Description of health condition studied
Chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Pain intensity and disability score in Oswestry questionnaire
Timepoint
Before Intervention and After end of Intervention and 1 month after end of intervention
Method of measurement
Oswestry questionnaire

2

Description

Pain intensity score in VAS (Visual Analogue Scale) questionnaire

Timepoint

Before Intervention and After the first intervention session and After end of Intervention and 1 month after end of intervention

Method of measurement

VAS (Visual Analogue Scale) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, Basilic vein venisection(FASD) will be prescribed and will be performed in two stages.The Scalpe(bistoury) used is number 11, the gap created is two to five millimeters and the amount of blood taken is about fifty to one hundred cc ans the venisection site will then be dressed. The basilic vein runs down the inside of the forearm. To perform the procedure, you must first find out where the artery is in the vein. If it is below the vein, which is often the case, the blade should be inserted so that only the upper surface of the vessel is opened longitudinally so that it does not reach the lower surface of the artery. The second phase of Fasd will be performed 2 weeks after the start of treatment.

Category

Treatment - Other

2

Description

Intervention group: Patients in the acupuncture group visit 10 sessions of acupuncture during regular planning. Acupuncture is performed three times a week for each person. Each treatment session lasts about 20 minutes when the localized points are connected to the electrode device and acupuncture is performed with electrical stimulation (electroacupuncture). The choice of localized points is made by the therapist (acupuncturist) according to the patient's condition and after the examination. In addition to the local points, the other points selected based on the references will be: DU4, UB23, UB40, Ki3, DU20The needles used will be 0.25 x 40.

Category

Treatment - Devices

3

Description

Control group: Patients in the physiotherapy group undergo regular sessions of 10 sessions to perform standard physiotherapy for chronic low back pain.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Moein Jamali

Street address

Keshavarz Blvd

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2

Recruitment center

Name of recruitment center

Ahmadiyeh Health College(School of Persian Medicine)

Full name of responsible person

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No. 27, Sarparast St, West Taleghani Ave, Felestin Sq

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3

Recruitment center

Name of recruitment center

Heravi Health College(School of Persian Medicine)

Full name of responsible person

Moein Jamali

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No. 67, West Jamali alley, Vafamanesh St., Heravi Sq

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd
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Postal code
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Phone
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Email
gsia@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Moein Jamali Dastjerdi
Position
Resident (PhD candidate)
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Yes - There is 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

Title and more details about the data/document

All data can be shared after people have not been identified

When the data will become available and for how long

Start the access period 6 months after the publication of the results

To whom data/document is available

Data will only be available to researchers working at academic and scientific institutions

Under which criteria data/document could be used

Any scientific use of the data with mentioning the reference is unrestricted

From where data/document is obtainable

Applicants can contact us via email below to receive data and any information Jamali.msb@gmail.com

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

After submitting the applicant's application and coordinating with the supervisor, the information plan will be provided to the applicant as soon as possible.

Comments