

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 Ahmadi 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)

Phone

+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 corticosteroids 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)

AgeFrom **30 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget 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 and 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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Postal code

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Phone

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Email

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2

Recruitment center

Name of recruitment center

Ahmadiyah Health College(School of Persian Medicine)

Full name of responsible person

Moein Jamali

Street address

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

Street address

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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Province

Tehran

Postal code

1416753955

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

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Karimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Mehrdadkarimi@yahoo.com

Person responsible for updating data

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

Traditional Medicine

Street address

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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