Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Basilic phlebotomy on sciatalgia and its comparison with classical medical treatment

Protocol summary

Study aim

The effect of Basilic phlebotomy on sciatalgia and its comparison with classical medical treatment

Design

Clinical practice Patients were randomly assigned to each other in two groups of control and case respectively Are included. One blind spot The two groups did not have any other knowledge of the other group Projected sample size: 50

Settings and conduct

Patients with Sciatic pain requiring non-surgical treatment referred to the health center of Shahed University of Medical Sciences were selected randomly and one blinded. A group of 100 and the second group are treated with diclofenac tablets

Participants/Inclusion and exclusion criteria

Sciatica pain requires non-surgical treatment Major reasons for not entering the study before randomization 35> BMI> 18 Fixed weight The desire to participate in a patient's study There is no history of surgical dislocations of the spine and severe sensory and motor pain Inflammatory back pain, rheumatism, ganglion and metabolic disorders, bad breaths, blood diseases and coagulation diseases, and pelvic abnormalities due to CDH or other spinal diseases such as scoliosis, kyphosis, spondylolisthesis, etc. Do not have anemia Not being treated with morphine or drug addiction Pregnant or lactating women. There is no history of fracture or surgery in the last three months. There is no history of any inflammatory disease of the joints, such as rheumatoid arthritis, rheumatic fever, and ankylosing spondylitis. The patient should not be cold and dry in a less than warm, dry environment No significant mental illness (such as schizophrenia). Do not stop taking Diclofenac tablets Not being treated with anticoagulants

Intervention groups

Sciatica pain requires non-surgical treatment

Main outcome variables

Evaluation of pain intensity in the two groups and their comparison before and after the study Evaluation of patients' quality of life in two groups and their comparison before and after study Assessing the disability of patients in two groups and comparing them before and after study

General information

Reason for update

Acronym

Fasd

IRCT registration information

IRCT registration number: **IRCT20180131038575N1**
Registration date: **2018-02-27, 1396/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-27, 1396/12/08**
Update count: **0**

Registration date

2018-02-27, 1396/12/08

Registrant information

Name

Mohammad Hasan Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3225 3374

Email address

mhassan.amini@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-04-21, 1397/02/01

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

Scientific title
The effect of Basilic phlebotomy on sciatalgia and its comparison with classical medical treatment

Public title
The effect of Basilic phlebotomy on sciatalgia and its comparison with classical medical treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Sciatica pain requires non-surgical treatment 35 > BMI >18 Fixed weight The desire to participate in a patient's study There is no history of surgical dislocations of the spine and severe sensory and motor pain Inflammatory back pain, rheumatism, ganglion and metabolic disorders, bad breaths, blood diseases and coagulation diseases, and pelvic abnormalities due to CDH or other spinal diseases such as scoliosis, kyphosis, spondylolisthesis, etc. Do not have anemia Not being treated with morphine or drug addiction Pregnant or lactating women. There is no history of fracture or surgery in the last three months. There is no history of any inflammatory disease of the joints, such as rheumatoid arthritis, rheumatic fever, and ankylosing spondylitis. The patient should not be cold and dry in a less than warm, dry environment No significant mental illness (such as schizophrenia). Do not stop taking Diclofenac tablets Not being treated with anticoagulants
Exclusion criteria:
Possible side effects of treatment Unwillingness to continue to participate in the plan. Irreparable aggravation of pain and disability.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned to each other in two groups of control and case respectively Are included.
Blinding (investigator's opinion)
Single blinded
Blinding description
The two groups did not have any other knowledge of the other group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahed University
Street address
University of Shahed University، facing the shrine Imam Khomeini، Persian Gulf Highway, Tehran
City
Tehran
Province
Tehran
Postal code
3319118651
Approval date
2017-05-31, 1396/03/10
Ethics committee reference number
IR.Shahed.REC.1396.27

Health conditions studied

1

Description of health condition studied
Sciatica pain
ICD-10 code
M00-M99
ICD-10 code description
Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before, one day, three days, ten days and four weeks after the scheduled time
Method of measurement
VAS questionnaire

Secondary outcomes

1

Description
Quality of Life
Timepoint

Before the start of the project and one month later (the end of the project)

Method of measurement

SF36 questionnaire

2

Description

Disability

Timepoint

Before the start of the project and one month later (the end of the project)

Method of measurement

Ronaldomiris questionnaire

3

Description

Generic temper

Timepoint

Before the start of the project and one month later (the end of the project)

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: phlebotomy

Category

Treatment - Other

2

Description

Control group: Taking 50 to 100 mg of diclofenac tablets based on patient weight (less than 60 kg), Alborz Medication will be placed twice a day for 7 to 10 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center of Traditional Medicine, Shahed University

Full name of responsible person

Mohammad Hasan Amini

Street address

No. 17، Arman Avenue، Dashtestan 3 Ave، Below Hoseinieh Ershad، Dr. Shariati Avenue، Tehran

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hasanamini78@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kyasalari

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info@shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Mohammad Hasan Amini

Position

Assistant Specialist in Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Seyyed Saeed Esmaeili Saber
Position
Iranian medicine specialist
Latest degree
Specialist
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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Full name of responsible person
Mohammad hasan Amini
Position
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Latest degree
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Other areas of specialty/work
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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