

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluating the effect of phlebotomy of "Al-Nesa" vein with diclofenac on the pain spread to the lower extremities

Protocol summary

Summary

The aim of this study was to compare the effect of diclofenac and phlebotomy of Al-nesa vein on the pain spread to the lower extremities. Patients with complaints of pains spread to lower extremities were enrolled in this study. Inclusion criteria included age 20 to 60 years, mechanical low back pain, a herniated disc between the vertebrae (including sciatic pain), osteoarthritis, spinal stenosis, spinal fractures, bad sit, scoliosis. Exclusion criteria included surgery for low back pain, infection, rheumatism, endocrine or metabolic-induced low back pain, tumors, hematologic diseases, mental illnesses, coagulation disease, surgery indication, referral pain from other organs, abnormal severity of pain, patient dissatisfaction, a history of faint subsequent to phlebotomy or wet cupping, contraindications of phlebotomy, BMI over 35. Patients will be randomly assigned in to two groups. The control group treated with diclofenac 100 mg (Albrzdaru company) for two weeks. Study group is treated with phlebotomy of "Al-nesa" vein. The used bistury blade is NO. 11, induced gap is 1-2 mm, volume of taken blood is 100-150 cc. The questionnaires including personal information and history of diseases, VAS, quality of life and standard of Roland Morris. The questionnaires are filled before treatment, two week, and one month after treatment. At the end of the study the results obtained from both groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101724557N1**

Registration date: **2015-11-16, 1394/08/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-16, 1394/08/25

Registrant information

Name

Mohamad Reza Morovati

Name of organization / entity

Tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 83 3722 7104

Email address

mreza13461346@yahoo.com

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of phlebotomy of "Al-Nesa" vein with diclofenac on the pain spread to the lower extremities

Public title

Effect of phlebotomy on the pain spread to the lower extremities

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 60 years old; mechanical low back pain: a herniated disc between the vertebrae (including sciatic pain); osteoarthritis; spinal stenosis; spinal fractures; bad sit; scoliosis. Exclusion criteria: surgery for low back pain; infection; rheumatism; endocrine or metabolic-induced low back pain; tumors; hematologic diseases; mental illnesses; coagulation disease; surgery indication; referral pain from other organs; abnormal severity of pain; patient dissatisfaction; a history of faint subsequent to phlebotomy or wet cupping; contraindications of phlebotomy; BMI over 35.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

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

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv.

City

Tehran

Postal code

Approval date

2015-09-24, 1394/07/02

Ethics committee reference number

IR.TUMS. REC.1394

Health conditions studied

1

Description of health condition studied

Pain radiating into the lower extremity (sciatica)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

low back pain

Timepoint

Baseline and two months later

Method of measurement

Wu Roland Morris questionnaire using VAS scale

Secondary outcomes

1

Description

Failure

Timepoint

Baseline and two months later

Method of measurement

Quality of life and standard questionnaire of Roland Morris

Intervention groups

1

Description

Phlebotomy group: phlebotomy "Al-nesa" vein on the lateral malleolus

Category

Treatment - Surgery

2

Description

Control group Tablets Alfen XL (diclofenac 100 mg) Alborz drug, twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences' Clinic

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Reza Morovati

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Tehran University of Medical Sciences, Keshvarz Blvd

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Reza Morovati

Position

MD, Assistant traditional medicine

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty