

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of small saphenous phlebotomy on pain due to sciatic neuropathy in patients with sciatic radicular pain: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of small saphenous phlebotomy on pain due to sciatic neuropathy in patients with sciatic radicular pain **Design:** a randomized clinical trial. **Setting and conduct:** The eligible patients with sciatic radicular pain who will refer to a private clinic during the study period will be enrolled into the trial. **Inclusion criteria:** (a) having neuropathy; (b) having degenerative disorder in vertebral column; (c) age of 18 to 65 years. **Exclusion criteria:** (a) having inflammatory, infective, psychiatry, hemorrhagic disorders of malignancy; (b) not being candidate for surgery. **Intervention:** small saphenous phlebotomy in the area between the external malleolus and the achilles tendon for 10 to 20 ml plus non-steroidal anti-inflammatory drugs three times a day for one month. **Control:** non-steroidal anti-inflammatory drugs three times a day for one month. **Primary outcome:** measuring the radicular pain severity before and one month after intervention using Neuropathic Pain Questionnaire (NPQ) and Neuropathic Pain Scale (NPS). **Secondary outcome:** measuring inflammatory gen activity (IL-1 β , IL-6, TNFR1, and TNF- α) before and one month after intervention using PCR

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501029014N51**

Registration date: **2015-01-07, 1393/10/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-01-07, 1393/10/17

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of small saphenous phlebotomy on pain due to
sciatic neuropathy in patients with sciatic radicular pain:
a randomized clinical trial

Public title

Effect of small saphenous phlebotomy on pain due to
sciatic neuropathy in patients with sciatic radicular pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) having neuropathy; (b) having

degenerative disorder in vertebral column; (c) age of 18 to 65 years. Exclusion criteria: (a) having inflammatory, infective, psychiatry, hemorrhagic disorders of malignancy; (b) not being candidate for surgery.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **230**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: random assignment of the patients systematically one at a time to intervention and control groups. Blinding: Not blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2014-12-30, 1393/10/09

Ethics committee reference number

P/16/35/9/4973

Health conditions studied

1

Description of health condition studied

sciatic radicular pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

measuring the radicular pain severity

Timepoint

before and one month after intervention

Method of measurement

using Neuropathic Pain Questionnaire (NPQ) and Neuropathic Pain Scale (NPS).

Secondary outcomes

1

Description

measuring inflammatory gen activity (IL-1 β , IL-6, TNFR1, and TNF- α)

Timepoint

before and one month after intervention

Method of measurement

Using PCR

Intervention groups

1

Description

small saphenous phlebotomy in the area between the external malleolus and the achilles tendon for 10 to 20 ml plus non-steroidal anti-inflammatory drugs three times a day for one month

Category

Treatment - Surgery

2

Description

non-steroidal anti-inflammatory drugs three times a day for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

A Private clinic

Full name of responsible person

Dr Hossein Mirzaei

Street address

A Private clinic, Rokni Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
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**

Non gvermental

Full name of responsible person

Dr Hossein Mirzaei

Position

General Pgysician

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Web page address

Person responsible for updating data

Contact

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