

# 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

**Street address**

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

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohamad Hossein Farzai

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

School of Pharmacy, Kermanshah

**City**

kermanshah

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mh.farzaei@gmail.com

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### 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*