

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The Effect of topical Henna (*Lawsonia inermis* L.) oil on pain in chronic sciatica patients; A double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Determine the effect of topical Henna oil on pain in chronic sciatica patients

##### Design

A randomized controlled clinical trial with parallel groups, double blinded

##### Settings and conduct

The research site is the neurosurgery clinic of Imam Khomeini Hospital and the health centers affiliated to the Faculty of Iranian Medicine of Tehran University of Medical Sciences. Chronic sciatica patients are randomly divided into 3 groups of henna oil (in sesame oil base), sesame oil and placebo. Patients in 3 groups use 10 drops of the oil or placebo, 3 times a day, for 4 weeks, topically on the low back and unilateral painful area from gluteal to middle posterior of thigh; and they can take one diclofenac 25 mg tablet up to 2 times a day, if they have severe pain. Patients and researchers are not aware of treatment allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic unilateral sciatica pain for at least 3 months and more; age 18 to 65 years; Pain score of 1 or more on visual analog scale; Willingness to participate in the study; Without communication problems; Not being candidate for surgery; No history of surgery in the low back; No history of alcohol and narcotic abuse; Body mass index between 18.5 to 34.9  
Exclusion criteria: Pregnancy or lactation; Severe allergy to any of the medications used in the study; Severe side effects; Unwillingness to continue participating in the study; No use of oils more than twice in a row; Acute illness or accident during the study; G6PD; Aggravation of pain; Use of other complementary and alternative therapies; Use of analgesics out of the study; Cauda equine syndrome; Symptoms require further investigation

##### Intervention groups

Intervention group1: To use topically henna oil (in sesame oil base); Intervention group2: To use topically sesame

oil; The Placebo group: To use topically mineral oil

##### Main outcome variables

Pain intensity

#### General information

##### Reason for update

Recruitment start date was corrected.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210919052522N1**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **1**

##### Registration date

2021-10-10, 1400/07/18

##### Registrant information

##### Name

Narges Lavari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8899 3656

##### Email address

n-lavari@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-11, 1400/07/19

##### Expected recruitment end date

2022-03-21, 1401/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of topical Henna (Lawsonia inermis L.) oil on pain in chronic sciatica patients; A double-blind randomized clinical trial

**Public title**

The Effect of topical Henna oil on pain in chronic sciatica patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with chronic unilateral sciatica pain (lumbar radiculopathy in this study defined chronic back pain that spread to a leg. Pain described as sharp, burning with numbness and/or tingling.) For at least 3 months and more Age 18 to 65 years Pain score of 1 or more on visual analog scale (VAS) of 0 to 10 Willingness of patients to participate in the study Patients without communication problems (vision, hearing, speaking and understanding) Pain not attributable to malignancy, inflammatory arthritis such as rheumatoid arthritis, or blood diseases and coagulation and infectious diseases Patients without congenital spinal abnormalities, bone fractures, scoliosis, kyphosis and spondylosis Patients are not candidate for surgery No history of surgery in the lower back No history of alcohol and narcotic abuse Body mass index(BMI) between 18.5 to 34.9

**Exclusion criteria:**

Pregnancy or lactation Severe allergy to any of the medications used in the study Severe side effects Unwillingness to continue participating in the study No use of oils more than twice in a row Occurring acute illness or accident during the study Patients with G6PD Aggravation of pain Use of other complementary and alternative therapies Use of analgesics out of the study during the study Cauda equine syndrome symptoms include numbness and weakness in both legs, pain in the anal area, perineal numbness, paralysis of the sphincters Symptoms require further investigation during the study

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **81**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation to groups is done by balance block randomization method with triple blocks(using the related table to random permutations). The randomized list is provided by a statistical consultant. In this way, the group code of each patient who enters the study (in the order of patient admission) is determined based on a randomized list. These codes, which belong to the three groups of henna oil(in sesame oil base) group and sesame oil group and the placebo group(mineral oil) have been determined by a statistical consultant; and in addition to patients, the researcher will not be informed until the end of the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Drugs and the placebo are packed in similar bottles with the same shape, color and smell. The proprietary codes set by the pharmacist on the bottle of drugs and the placebo. Patients and the researcher are not aware of codes.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Sixth Floor, Central Office of Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2021-09-19, 1400/06/28

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1400.671

**Health conditions studied****1****Description of health condition studied**

Chronic sciatica

**ICD-10 code**

M00-M99

**ICD-10 code description**

Diseases of the musculoskeletal system and connective

tissue

## Primary outcomes

### 1

#### Description

Pain intensity

#### Timepoint

At the beginning of the study (before the intervention) and 7, 14 and 28 days after the start of the study

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Diclofenac tablets taken daily

#### Timepoint

during study

#### Method of measurement

Number

### 2

#### Description

Disability

#### Timepoint

Before the start of the study and 4 weeks after the start of the study(the end of the study)

#### Method of measurement

Oswestry disability questionnaire

### 3

#### Description

Quality of Life

#### Timepoint

Before the start of the study and 4 weeks after the start of the study(the end of the study)

#### Method of measurement

The Short form health survey 36 questionnaire (SF-36)

### 4

#### Description

Skin side effects

#### Timepoint

Days 3, 7, 14 and 28 days after the start of the study

#### Method of measurement

Form of skin side effects based on CTCAE(Common Terminology Criteria for Adverse) version 5

## Intervention groups

### 1

#### Description

First intervention group: Chronic sciatica patients use topically 10 drops(half a cc) of henna oil(in sesame oil

base) on the low back and unilateral painful area from gluteal to middle posterior of thigh without massage, 3 times a day, for 4 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Second intervention group: Chronic sciatica patients use topically 10 drops(half a cc) of sesame oil on the low back and unilateral painful area from gluteal to middle posterior of thigh without massage, 3 times a day, for 4 weeks.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Chronic sciatica patients use topically 10 drops(half a cc) of mineral oil on the low back and unilateral painful area from gluteal to middle posterior of thigh without massage, 3 times a day, for 4 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahmadih Persian Medicine Health Center in Tehran University of Medical Sciences.

##### Full name of responsible person

Narges Lavari

##### Street address

No.27, School of Traditional Medicine, Sarparast St., Taleghani Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1416663361

##### Phone

+98 21 8897 4535

##### Email

spm@tums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Narges Lavari

##### Street address

Imam Khomeini Hospital, Dr. Gharib Ave., Keshavarz Blvd.

##### City

Tehran

**Province**  
Tehran  
**Postal code**  
1419733141  
**Phone**  
+98 21 6119 2755  
**Email**  
lmamhospital@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Alireza Abbassian  
**Street address**  
No.27, School of Traditional Medicine, Sarparast St.,  
Taleghani Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 3656  
**Email**  
abbasian@sina.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**  
Narges Lavari  
**Position**  
PhD student in Persian Medicine  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

Traditional Medicine  
**Street address**  
No.27, School of Traditional Medicine, Sarparast St.,  
Taleghani Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 3656  
**Fax**  
**Email**  
n-lavari@razi.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Narges Lavari  
**Position**  
PhD student in Persian Medicine  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
No.27, School of Traditional Medicine, Sarparast St.,  
Taleghani Ave.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 3656  
**Fax**  
**Email**  
n-lavari@razi.tums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Narges Lavari  
**Position**  
PhD student in Persian Medicine  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
No.27, School of Traditional Medicine, Sarparast St.,  
Taleghani Ave.  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
1416663361  
**Phone**  
+98 21 8899 3656  
**Fax**  
**Email**  
n-lavari@razi.tums.ac.ir

## 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