

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)

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+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

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Province

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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

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

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
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Narges Lavari
Position
PhD student in Persian Medicine
Latest degree
Medical doctor
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Person responsible for updating data

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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