Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 between18.5 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

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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
Ahmadieh 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
Name of organization / entity
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Full name of responsible person
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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
Full name of responsible person
Narges Lavari
Position
PhD student in Persian Medicine
Latest degree
Medical doctor
Other areas of specialty/work
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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