Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the topical application of Hemiscorpius lepturus oil prepared based on the sources of Iranian traditional medicine on the pain of chronic sciatica patients: A double-blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of topical use of ordinary Gadim scorpion oil, prepared based on Iranian traditional medicine sources, on the pain of patients with chronic sciatica in the form of a double-blind randomized clinical trial.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized on 84 patients.

Settings and conduct

The current study is a double-blind randomized clinical trial study (no patient and researcher information) on 84 patients with chronic sciatica disease for 4 weeks at the Tehran Traditional Medicine Research Center (Salamtakdeh Ahmadiyya). How to use the topical ointment: 3 times a day (morning, noon, night), each time, the size of 2 knuckles will be applied in the lower back area (from L1 down), buttock area to the middle of the back of the thigh on the side that hurts, along with massage. .

Participants/Inclusion and exclusion criteria

Entry criteria: 1- A patient with chronic sciatica pain that lasts for at least 3 months 2- Age over 18 years 3- Pain equivalent to 1 or more based on the VAS criteria and 4- Patients willing to cooperate in the study 5- Absence of any history of surgery in the lower back area 6- Not having a history of alcohol and narcotic drug use 7-18.4 <BMI<35 Exclusion criteria 1- Pregnancy or breastfeeding 2- Severe side effects 3- Severe sensitivity to any of the drugs used in the study 4- Dissatisfaction to continue participating in the study 5- Patients with a history of lumbar disc surgery 6- Exacerbation of the patient's pain and its lack of control 7- Use of painkillers outside of the study program during the study.

Intervention groups

The intervention group received topical ointment containing scorpion oil and the control group received ointment containing liquid paraffin (placebo).

Main outcome variables

Severity of leg and back pain

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20241004063253N1**
Registration date: **2024-10-13, 1403/07/22**
Registration timing: **prospective**

Last update: **2024-10-13, 1403/07/22**
Update count: **0**

Registration date

2024-10-13, 1403/07/22

Registrant information

Name

Amir hossein Kia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-01, 1403/08/11

Expected recruitment end date

2025-03-14, 1403/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the topical application of Hemiscorpius lepturus oil prepared based on the sources of Iranian traditional medicine on the pain of chronic sciatica patients: A double-blind randomized clinical trial

Public title

Investigating the local effectiveness of ordinary gadim scorpion oil on the pain of patients with chronic sciatica

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- A patient with chronic sciatica pain (chronic lumbar radiculopathy, which is defined in this study as low back pain (from the L1 region and below it in the lower back region) which spreads unilaterally to one leg and sharp, burning pain with numbness and with or without tingling.) to continue for at least 12 weeks or more.2- Age above 18 years3- Pain equivalent to 1 or more based on VAS criteria4- Willingness of patients to cooperate in the study5- People without communication problems (sight, hearing, speaking and understanding).6- Pain that is not due to malignancies, inflammatory joint and rheumatic diseases such as rheumatoid arthritis, blood diseases and coagulation and infectious diseases.7- Don't have congenital abnormalities of the spine, bone fractures, scoliosis, kyphosis and spondylosis.8- Not a candidate for surgery.9- Absence of any history of surgery in the back area10- Not having a history of alcohol and narcotic drugs11-18.4 <BMI<35

Exclusion criteria:

1- Pregnancy or breastfeeding2- causing severe side effects3- Severe sensitivity to any of the drugs used in the study4- Lack of consent to continue participating in the study5- Patients with a history of lumbar disc surgery6- Concurrent acute illness or accident during the study7- People suffering from favism8- Intensification of the patient's pain and its lack of control9- Using non-pharmacological pain relief treatments from any medical school such as acupuncture, massage, yoga, etc.10- Use of painkillers outside the study program during the study11- Symptoms of horse tail syndrome include numbness and weakness of both legs, numbness of the perineum, pain in the anal area, paralysis of the sphincters.12- Occurrence of clinical symptoms during the treatment that, in the doctor's opinion, require further investigation.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Random block method is used to divide people into two groups. The first group uses oleogel containing scorpion oil and placebo (oleogel without scorpion oil) is used on the second group. Simple Random Sampling (Simple Random Sampling) is one of the statistical sampling methods in which people in the community have an equal chance of being selected. In this method, each element of the desired statistical population has an equal chance to be selected. In this method, the needed people or objects are randomly selected from the list of the statistical population that is numbered and prepared for this purpose. According to the law of probability, the selected people should have the same characteristics as the society from which they were selected. The advantage of the authentication block method is the balance of the number of participants in two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicines and placebo are in similar tubes with the same shape, color and smell. The specific codes are written by the pharmacist on the label of the medicine container and the placebo so that the patients and the researcher do not know the meaning of the codes.

Placebo

Used

Assignment

Parallel

Other design features

Due to compliance with ethical principles and not depriving patients of common treatments, study participants (both groups) can take diclofenac 25 mg tablets up to 2 times a day, one at a time, if they feel the need and have severe pain. As much as medicinal ointment is more effective than placebo on the pain intensity of patients, the amount of oral pain reliever (diclofenac) should be lower in the first group than in the second group (placebo ointment recipient). Accordingly, the participants are asked to write down the number of diclofenac consumed per day and finally inform the presenter.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Alborz University of Medical Sciences

Street address

Deputy Research Building., Shahid Safarian Alley., 45-

meter Golshahr St., Karaj

City
Karaj

Province
Alborz

Postal code
3198764653

Approval date
2024-09-18, 1403/06/28

Ethics committee reference number
IR.ABZUMS.REC.1403.151

Health conditions studied

1

Description of health condition studied
Chronic Sciatica

ICD-10 code
M00-M99

ICD-10 code description
Disease of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Severity of leg and back pain

Timepoint
at the beginning of the study (before the start of the intervention) and 7, 14, 21 and 28 days after the start of the study

Method of measurement
Visual Analogue Scale for leg and back pain intensity

Secondary outcomes

1

Description
The degree of disability of patients

Timepoint
before the start of the study and 4 weeks after the start of the study (end of the study)

Method of measurement
Questionnaire Oswestry Disability Index

2

Description
The number of diclofenac tablets taken daily

Timepoint
Length of study

Method of measurement
number

3

Description
Skin Adverse effect

Timepoint
Days 3, 7, 14, 21 and 28 after the start of the study

Method of measurement
Skin side effects form based on CTCAE version 5 (Common Terminology Criteria for Adverse effects)

Intervention groups

1

Description
Intervention group: Recipient of topical ointment containing scorpion oil: 3 times a day (morning, noon, night) each time in the size of 2 knuckles in the lumbar area (from L1 down), buttock area to the middle of the back of the thigh on the side that hurts, for 4 The week will be rubbed along with the massage. If they feel the need and have severe pain, they can take diclofenac 25 mg tablets up to 2 times a day, one at a time.

Category
Treatment - Drugs

2

Description
Control group: recipient of topical ointment containing liquid paraffin: 3 times a day (morning, noon, night) each time the size of 2 knuckles in the lumbar region (from L1 down), buttock region to the middle of the back of the thigh on the side that has pain. It will be applied for 4 weeks along with massage. If they feel the need and have severe pain, they can take diclofenac 25 mg tablets up to 2 times a day, one at a time.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Traditional Medicine Research Center (Salam Takdeh Ahmadiyya located on Khodaparast St.)

Full name of responsible person
Alireza abbasian

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No. 42, Next to the Tabriz Alley, North Sarparast Ave, Tehran

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
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Position
Non-faculty student
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A Level or less
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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