Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effectiveness of topical use of Black fat-tailed scorpion oil (Androctonus crassicauda) on the pain of patient with chronic sciatica: A double-blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of topical application of black broad tail scorpion oil on pain in patients with chronic sciatica

Design
A parallel-group, double-blind, randomized clinical trial

Settings and conduct
The place of study is Tehran Traditional Medicine Research Center (Ahmadiyeh Health Center located on Khodaparast Street). The present study is a double-blind randomized clinical trial study. The study is conducted on 84 patients with chronic sciatica for 4 weeks. The study is double-blind (lack of knowledge of the patient and the researcher). How to use topical ointment: 3 times a day (morning, noon, night) each time in the size of 2 knuckles in the lower back area (from L1 down), buttock area to the middle of the back of the thigh on the side that hurts, for 4 weeks along with The massage will be rubbed. Also, 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 if they feel the need and severe pain.

Participants/Inclusion and exclusion criteria
-Entry criteria: 1-Patient with sciatica pain that lasts for at least 12 weeks 2-Age over 18 years 3-Pain equal to 4 or more based on VAS criteria 4-Not a candidate for surgery 5-Lack of any surgical history Exclusion criteria: 1-Pregnancy or breastfeeding 2-Creating severe side effects 3-Severe sensitivity to any of the drugs used in the study 4-Not agreeing to continue participating in the study 5-Intensification of the patient's pain and lack of control

Intervention groups
The first group received medicated ointment containing scorpion oil and the second group received placebo ointment containing liquid paraffin.

Main outcome variables
Severity of leg and back pain with the Visual Analogue Scale

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20240916063059N1**
Registration date: **2024-10-17, 1403/07/26**
Registration timing: **prospective**

Last update: **2024-10-17, 1403/07/26**
Update count: **0**

Registration date
2024-10-17, 1403/07/26

Registrant information

Name
Yaیزدانzdan Amini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-05, 1403/08/15

Expected recruitment end date
2025-03-04, 1403/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of topical use of Black fat-tailed scorpion oil (Androctonus crassicauda) on the pain of patient with chronic sciatica: A double-blind randomized clinical trial

Public title

Investigating the topical effectiveness of Black fat-tail scorpion oil on pain in patients with chronic sciatica

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Patient with chronic sciatica pain for at least 12 weeks 2- Age above 18 years 3- Pain equivalent to 4 or more based on VAS criteria 4- Willingness of patients to cooperate in the study 5- People without communication problems. 6- Pain that is not due to malignancies, inflammatory joint diseases, etc. 7- Don't have congenital abnormalities of the spine and bone fractures. 8- Not a candidate for surgery. 9- Absence of any history of surgery in the back area 10- Not having a history of alcohol and narcotic drugs 11- BMI between 18.4 and 35

Exclusion criteria:

1- Pregnancy or breastfeeding 2- causing severe side effects 3- Severe sensitivity to any of the drugs used in the study 4- Lack of consent to continue participating in the study 5- Patients with a history of lumbar disc surgery 6- Concurrent acute illness or accident during the study 7- People suffering from favism 8- Intensification of the patient's pain and its lack of control 9- Use of non-pharmacological soothing treatments 10- Use of painkillers outside the study program during the study 11- Symptoms of cauda equina syndrome 12- Occurrence of serious clinical symptoms during treatment

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.1403.150

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 number of diclofenac tablets taken daily
Timepoint
Length of study
Method of measurement
number

2

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

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Doctor Mohammad Mahdi Ahmadian
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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
Yazdan Amini

Position
Non-faculty student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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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