Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigating the effect of topical Boswellia oil on pain severity in patients with lumbar disc herniation

Protocol summary

Study aim
Determining the effect of topical use of frankincense oil on the pain intensity of patients with lumbar disc herniation referred to neurologists' office in Rafsanjan

Design
The study used accessible random sampling, grouping based on pain scores and gender. Group sizes were equalized with random minimization. Sampling continued until reaching the desired size. Sample size in each group was determined to be 27.67, considering potential losses.

Settings and conduct
The research population was all patients with lumbar disc herniation who referred to the office of neurologists in Rafsanjan city.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Age between 20 and 60 years 2- Not suffering from nervous and mental diseases 3- Lumbar disc herniation based on neurologist and MRI diagnosis .. Exclusion criteria: 1- Desire to quit studying 2- The need for surgery during the study 3- The need to inject coronet during the study ..

Intervention groups
In the intervention group, the patients were taught to use 10 drops of frankincense oil topically twice a day for 6 weeks. In the control group, olive oil was used as a placebo in the pain area. 30 ml droppers containing olive oil, in the same packaging, for local use, were provided to patients in the placebo group.

Main outcome variables
Evaluation of the effect of frankincense oil on pain, level of effectiveness of frankincense oil, tolerability and side effects, relationship with images of treatment exacerbation, suggestions for prescribing the best treatment, economic effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230919059473N1**
Registration date: **2023-10-09, 1402/07/17**
Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**
Update count: **0**

Registration date
2023-10-09, 1402/07/17

Registrant information

Name
Fatemeh Tavakoli

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
2023-10-17, 1402/07/25

Expected recruitment end date
2024-01-15, 1402/10/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of topical Boswellia oil on pain severity in patients with lumbar disc herniation

Public title
effect of topical Boswellia oil on pain severity in patients with lumbar disc herniation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 60 years Not suffering from nervous and mental diseases Lumbar disc herniation based on neurologist and MRI diagnosis Lack of sensitivity to frankincense oil Not having wounds and lesions at the place of use Absence of diabetes mellitus Absence of absolute rest Absence of immune system problems in a person such as lupus erythematosus, multiple sclerosis (MS) Not having a history of surgery in the back area Absence of alcohol and drug addiction Not using other complementary methods for pain relief Not taking anticoagulants Absence of pregnancy and breastfeeding The amount of pain is more than 3 on the numerical-visual scale of VAS
Exclusion criteria:
Desire to quit studying The need for surgery during the study The need to inject coronet during the study Not performing intervention for more than two consecutive days or one alternate week Change or exacerbation of back pain Incidence of sensitivity and allergy during the implementation of the study, which is characterized by symptoms such as skin rashes.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method was accessible and randomly assigned to groups, classified based on important intervening variables, including pain score at the time of entering the study and gender. The number of samples in the groups was equal. In order to control the confounding factors and ensure the same number of samples in the groups, the random minimization method was used (table below). The first and second samples were randomly entered into the groups, and in the rest of the cases, attention was paid to the sum of the indicators in the groups. Sampling continued until the desired sample volume was reached.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients were completely unaware of which intervention group they were in. But they were aware of participating in the intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Rafsanjan University of Medical Sciences
Street address
Rafsanjan University of Medical Sciences - Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2023-05-03, 1402/02/13
Ethics committee reference number
IR.RUMS.REC.1402.018

Health conditions studied

1

Description of health condition studied
Patients with lumbar disc herniation
ICD-10 code
M51.86
ICD-10 code description
Other intervertebral disc disorders, lumbar region

Primary outcomes

1

Description
Evaluation of the effect of frankincense oil on pain: This study can show whether the local consumption of frankincense oil makes a significant change in the pain intensity of lumbar disc herniation patients.
Timepoint
Immediately after the end of the intervention
Method of measurement
Visual Pain Scale Questionnaire (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, 30 ml droppers containing 10% frankincense oil (prepared in the laboratory of the Faculty of Iranian Medicine, Kerman University of Medical Sciences) for topical use were provided to the patients. The patients were taught to use 10 drops (Razavi et al., 2019) of frankincense oil topically, twice a day for 6 weeks. It was explained to the patients that they should first massage the pain area a little and when they feel heat, put the oil on the massage area for a maximum of one minute. If the patient himself is not able to use the oil in the pain area, the second person should do it for him.

Category

Treatment - Other

2

Description

In the control group, olive oil was used as a placebo in the pain area. 30 ml droppers containing olive oil, in the same packaging, (prepared in the laboratory of the Faculty of Iranian Medicine, Kerman University of Medical Sciences) for topical use, were provided to patients in the placebo group. The method of use is similar to the conditions of using frankincense oil. It was emphasized to the patient to use the drops without interruption and at specified intervals. To reduce the possibility of forgetting, the patients were asked to use the oil at the same times and set a reminder on their mobile phones to remind them when to use the drops. The number of times and how the oil was consumed was tracked by the researcher once a week by phone and recorded in the relevant form.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rafsanjan Health Clinic

Full name of responsible person
Dr. Karmi

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Pistachio Boulevard in front of Tare Bar Square - Fars Gulf Boulevard - Rafsanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

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
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Fatemeh Tavakoli

Position
Nursing master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Full name of responsible person
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Department of Medical Surgical Nursing, School of Nursing and Midwifery, Rafsanjan University of Med

Latest degree
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Geriatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
In the analysis section, only output data and main results can be shared

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
It will be available only for researchers working in academic and scientific institutions, or people who are also working in industry can apply to receive them.

Under which criteria data/document could be used
The data is available only to clarify the methodology of the present study

From where data/document is obtainable
Dr. Shahin Heydari - Rafsanjan University of Medical Sciences

What processes are involved for a request to access data/document
An email should be sent to Dr. Shahin Heydari, and as soon as the email is seen, and at her discretion, it will be sent within 10 working days.

Comments