

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of Liliium candidum oil effect on pain and disability of people with back pain.

Protocol summary

Study aim

Lilium candidum oil effect on pain and disability of people with back pain

Design

Randomized, double blinded, clinical trial with parallel groups

Settings and conduct

The study will be carried out at Imam Reza Hospital in Tehran. All groups receive medicines in the same container and they do not know about contents. After confirming non-specific back pain by physician which does not know the type of medication; randomly select a coded container for treatment. The questionnaires will be analyzed after receiving and converting into numbers, by someone who does not know the title of study.

Participants/Inclusion and exclusion criteria

All male and female 20 to 55 aged patients who they are willing to be cooperative and they have symptoms of back pain for more than 3 months and they have pain at the time of entering to the study will be included. Patients are excluded from project by reporting the following: previous history of cancer, history of chronic infection, history of trauma, urinary incontinence, history of corticosteroid use, progressive neurological history, fever without justification, weight loss without justification, pain in the spine, abdominal mass, rectum, pelvis, patricide or heel foot, test for direct and retrograde stretch marks, sign Progressive focal neurons. Patients who have been treated with other drugs or who are present in other research projects will be excluded from the study.

Intervention groups

In group 1, 120cc of liliium oil in the similar cans as the other groups used for four weeks with daily intake at bedtime in the pain spot. In group 2, 120cc of sesame oil in the similar cans as the other groups used for four weeks with daily intake at bedtime in the pain spot. In group 3, 120cc of diclofenac gel in the similar cans as the other groups used for four weeks with daily intake at

bedtime in the pain spot.

Main outcome variables

Pain; Satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171010036691N2**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

saeed Rasoulinezhad

Name of organization / entity

Aja medical university

Country

Iran (Islamic Republic of)

Phone

+98 21 4382 2051

Email address

saeed.rasoulinezhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Aja university of medical science

Expected recruitment start date

2018-03-16, 1396/12/25

Expected recruitment end date

2018-04-14, 1397/01/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of Liliium candidum oil effect on pain and disability of people with back pain.

Public title
The effect of lily oil on pain and disability

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Male and female Patients Patients aged 20 to 55 years
 Having symptoms of back pain for more than 3 months
 Having back ache at the time of entering to the study
Exclusion criteria:
 Previous history of cancer History of chronic infection
 History of trauma Urinary incontinence History of corticosteroid usage Progressive neurological history
 Pain in the spine Abdominal, rectum and pelvis mass
 Patricide or heel foot Sign Progressive focal neurons
 Patients treated with other medications Patients that present in other research projects

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method, individual randomization unit, randomization tool: random number table

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the use of medication is topically. All groups receive medicines in the same container and they do not know about contents. After confirm non-specific back pain by physician which does not know the type of medication; randomly select a coded container. The questionnaires are analyzed after receiving and converting into numbers, by someone who does not know the type of test.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Aja University Of Medical sciences

Street address

Shahid etemad zade Ave., Fatemi Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.AJAUMS.REC.1396.65

Health conditions studied

1

Description of health condition studied

Back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

Pain

Timepoint

At the Beginning Of The Study, The Second, Fourth And Eighth Weeks

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Satisfaction

Timepoint

At the Beginning Of The Study, The Second, Fourth And Eighth Weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

In group 1, 120cc of liliun oil in the similar cans as the other groups used for four weeks with daily intake at bedtime in the pain spot.

Category

Treatment - Drugs

2

Description

In group 2, 120cc of sesame oil in the similar cans as the other groups used for four weeks with daily intake at bedtime in the pain spot.

Category

Treatment - Drugs

3

Description

In group 3, 120cc of diclofenac gel in the similar cans as the other groups used for four weeks with daily intake at bedtime in the pain spot.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Nafiseh hosseini yekta

Street address

Etemadzadeh Ave., Fatemi Ave, Tehran

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Email

nhyekta@yahoo.com

Web page address

<http://imamreza.ajaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Aja Medical University

Full name of responsible person

Armin zareian

Street address

Etemad zade Ave, Fatemi Ave, Tehran

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Phone

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Email

a.zareian@ajaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Aja Medical University

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

Artesh University of Medical Sciences

Full name of responsible person

Saeed rasoulinezhad

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Nafise Hosseiniyekta

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

saeed rasoulinezhad

Position

Student

Latest degree

Specialist