

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the effect of application of kharatin oil on the improvement of spasticity of patients with neurological disorders

Protocol summary

Study aim

Determining the effect of using kharatin oil on improving spasticity in patients with neurological disorders

Design

A clinical trial with a control group, with parallel groups, one-way, blind, randomized, on 50 patients, used the random function of Excel software rand for randomization.

Settings and conduct

This study is a pilot and one-way blind clinical trial. The study was performed on 50 patients with spasticity disorder who are hospitalized in the neurology ward. For three months, topical treatment with kharatin oil and the control group are treated with paraffin oil during the same period. The patient is also blind to being in the drug or placebo group.

Participants/Inclusion and exclusion criteria

Existence spasticity disorder- Sensitivity to kharatin oil

Intervention groups

50 people are included in the study as a pilot and after collecting the complete statistical population by drawing 25 people in the intervention group (patients with spasticity Treatment with kharatin oil) and the remaining 25 patients in the control group (patients with spasticity treated with paraffin oil).

Main outcome variables

Quality of Life, paraletic limb function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210806052093N1**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

Registration date

2021-08-16, 1400/05/25

Registrant information

Name

Mona Arab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3213 2152

Email address

m_arab@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of application of kharatin oil on the improvement of spasticity of patients with neurological disorders

Public title

The effect of kharatin oil on improving limb stiffness in patients with neurological disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of spasticity disorder

Exclusion criteria:

Sensitivity to kharatin oil

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant is blind. The drug and placebo are randomly distributed and recorded among the participants without a label and in identical envelopes by the project partner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman university of medical sciences

Street address

Kowsar Blvd, Shafa hospital

City

kerman

Province

Kerman

Postal code

7618751151

Approval date

2021-07-12, 1400/04/21

Ethics committee reference number

IR.KMU.REC.1400.245

Health conditions studied

1

Description of health condition studied

Tropical spastic paraplegia

ICD-10 code

G04.1

ICD-10 code description

Tropical spastic paraplegia

2

Description of health condition studied

Spastic hemiplegia

ICD-10 code

G81.1

ICD-10 code description

Spastic hemiplegia

3

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

4

Description of health condition studied

Neuromyelitis optica

ICD-10 code

G36.0

ICD-10 code description

Neuromyelitis optica [Devic]

5

Description of health condition studied

Hypoxic ischemic encephalopathy

ICD-10 code

P91.60

ICD-10 code description

Hypoxic ischemic encephalopathy [HIE], unspecified

6

Description of health condition studied

Spondylolysis cervical

ICD-10 code

M43.02

ICD-10 code description

Spondylolysis, cervical region

Primary outcomes

1

Description

Paralysis performance score in modified ashworth scale questionnaire

Timepoint

At the beginning of the study and 3 months after starting to use kharatin oil and paraffin

Method of measurement

modified ashworth scale questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

At the beginning of the study and 3 months after consuming kharatin oil and paraffin

Method of measurement

World Health Organization Quality of Life Questionnaire

Intervention groups

1

Description

Intervention group: 25 people in the intervention group who have spasticity disorder are treated topically with standard Aral kharatin oil made in Iran for 3 months. First, the limb with spasticity is washed with soap and water to be completely clean, and after washing, gently Massage the desired limb for 10 minutes until the skin color turns red to some extent. Then pour a few drops of kharatin oil on the limb and start a gentle massage until the oil is completely absorbed by the skin. Massage time is at least 5 minutes and up to 10 minutes. And twice a day. At least an hour after that, the oil should remain on the skin and not be washed.

Category

Treatment - Drugs

2

Description

Control group: 25 people in the control group who have spasticity disorder are treated topically with paraffin oil for 3 months. First, the limb with spasticity is washed with soap and water to be completely clean, and after washing, gently Massage the desired limb for 10 minutes until the skin color turns red to some extent. Then pour a few drops of paraffin oil on the limb and start a gentle massage until the oil is completely absorbed by the skin. Massage time is at least 5 minutes and up to 10 minutes. And twice a day. At least an hour after that, the oil should remain on the skin and not be washed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Hossein Ali Ebrahimi

Street address

Kowsar Blvd, Shafa Hospital

City

Kerman

Province

Kerman

Postal code

7618751151

Phone

+98 34 3211 5780

Email

hebrahimi@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Haft Bagh Alavi Blv, Campus of University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7618751151

Phone

+98 34 3132 5041

Email

abpardakhty@kmu.ac.ir

Web page address

Grant name

Vice Chancellor for Research and Technology of Kerman University of Medical Sciences

Grant code / Reference number

411389339391

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mona Arab

Position

neurology resident
Latest degree
Medical doctor
Other areas of specialty/work
Neuroscience
Street address
Kowsar Blvd, Shafa Hospital
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34 3211 5780
Email
monaarb68@gmail .com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Rostam Seifaddini
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neuroscience
Street address
Kowsar Blvd-Shafa Hospital
City
كرمان
Province
Kerman
Postal code
7618751151
Phone
+98 34 3211 5780
Email
r.seifaddini @gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mona Arab
Position
Neurology Resident
Latest degree

Medical doctor
Other areas of specialty/work
Neuroscience
Street address
Kowsar Blvd-Shafa Hospital
City
Kerman
Province
Kerman
Postal code
7618751151
Phone
+98 34 3211 5780
Email
Monaarb68@gamil.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

The results of extracting the modified ashworth scale questionnaire about the subjects can be shared after identifying the subjects.

When the data will become available and for how long

After taking medication and placebo and completing the modified ashworth scale questionnaire

To whom data/document is available

Faculty members of medical universities throughout Iran

Under which criteria data/document could be used

With a written request to reuse the files

From where data/document is obtainable

Postal address: Kerman, Kowsar Blvd., Shafa Hospital,
Mona Arab E-mail address: Monaarb68@gmail.com
Phone number: 09131435195

What processes are involved for a request to access data/document

The written and official request of the applicant, which has been approved by the Vice Chancellor for Research of the University of the applicant's place of work, will be sent within one week at the latest.

Comments