

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of an herbal nasal spray (an Iranian traditional medicine drug) based on oregano on migraine: A randomized, double-blinded, clinical trial

Protocol summary

Study aim

Determination of effect of herbal nasal spray based on Oregano on Migraine headache

Design

Two arm parallel group randomized control clinical trial, double-blind, phase 3. 70 patients, Block Random Allocation.

Settings and conduct

Among patients who come to Persian Medicine clinic of Tehran University, the patients who have migraine headache based on IHS criteria; are informed about the survey and if willing they are clearly informed about the procedure. After informed consent they are randomly entered in drug and placebo groups. A note book is designed for them to enter their headache information in that: the time and duration of headache, analgesic name and number used while headache, probable side effects. Finishing the survey the recorded information are investigated and beside Health-related quality of life tests are calculated as final results.

Participants/Inclusion and exclusion criteria

Entrance criteria: 1. Migraine headache based on IHS 2. 2 to 8 attacks per month with headache days less than 15 per month 3. Onset of headaches no sooner than a year ago 4. No warm brain temperament 5. age between 18 and 65 with onset of headaches sooner than 50 years old
Exclusion criteria: 1. Secondary headache 2. Antipsychotic and antidepressant drug for reasons other than migraine in last 3 months 3. Alcohol or drug abuse 4. Drug sensitivity to the drug in experiment ingredients 5. Fertile women with no contraception 6. Pregnancy and breast feeding 7. using a drug which could affect migraine headache during last week 8. drug overuse based on IHS criteria 9. Severe physical or psychological disease

Intervention groups

Drug and placebo spray

Main outcome variables

Number of Migraine headache attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220601055051N1**

Registration date: **2023-02-03, 1401/11/14**

Registration timing: **prospective**

Last update: **2023-02-03, 1401/11/14**

Update count: **0**

Registration date

2023-02-03, 1401/11/14

Registrant information

Name

Jila Naseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4535

Email address

j_n_30@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of an herbal nasal spray (an Iranian traditional medicine drug) based on oregano on migraine: A randomized, double-blinded, clinical trial

Public title
Effect of Oregano nasal spray on migraine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Migraine based on IHS criteria 2 to 8 migraine attack in a month with less than 15 days headache a month and with at least 48 hours intervals Onset of headaches less than one year ago No warm brain temperament 18 to 65 years old with headache onset no later than 50 years old
Exclusion criteria:
Secondary headaches Regular use of antipsychotic or antidepressant drugs during last 3 months for reasons other than migraine Alcohol or drug abuse Drug sensitivity to the drug ingredients Fertile women with no contraception Pregnancy and breast feeding consuming drugs affecting migraine headache or interacting with drug ingredients during last week Analgesic overuse based on IHS criteria Severe physical or psychological disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Random Allocation Two groups A and B randomly are allocated to intervention and control groups and are again randomly used in quadruple groups each with two A and two B groups arranged in all different possible arrangement that is: AABB, BBAA, ABAB, BABA, ABBA, BAAB A and B are in sealed envelope and handed to patients; and so they are randomly entered in two groups . Randomization unit is individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
The procedure is clearly explained to the patients and then they are given the drugs while they have no idea which drug, the real or the placebo is given to them; so patients are blind. The investigator who hands in the drugs to the patients does not know which drugs are real and which are placebos; so the investigator is blind, too.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

TUMS research ethics committee

Street address

sixth floor, Ghods st., Keshavarz Bulvar

City

Tehran

Province

Tehran

Postal code

research@tums.ac.ir

Approval date

2022-11-16, 1401/08/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.580

Health conditions studied

1

Description of health condition studied

Migraine headache

ICD-10 code

G43

ICD-10 code description

G43.0Migraine without aura [common migraine]

Primary outcomes

1

Description

Number of migraine headache attacks per month

Timepoint

Three times with one month intervals

Method of measurement

Number of attacks with at least 48 hours of freedom from headache between migraine attacks

Secondary outcomes

1

Description

Headache severity

Timepoint

Tree times with one month intervals

Method of measurement

Four point verbal scale

2

Description

Number and name of analgesics used

Timepoint

Three times with one month intervals

Method of measurement

Recording the name and the number of analgesics used in one month

3

Description

Health related quality of life

Timepoint

Three times with one month intervals

Method of measurement

Sf 36 & hit 6 questionnaire

Intervention groups

1

Description

Intervention group: herbal nasal spray based on oregano-three times a day one puff each nasal orifice

Category

Treatment - Drugs

2

Description

Control group: placebo nasal spray-three times a day one puff each nasal orifice

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran medical University Persian medicine clinic

Full name of responsible person

Dr Meysam Shirzad

Street address

Ahmadiieh Persian medicine clinic, Tabriz St., North sarparast St., Talrghani St., Felestine Square.

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spm@tums.ac.ir

Web page address

<https://spm.tums.ac.ir/contact-us.html>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotuhi

Street address

No 27, Sarparast St., Taleghani St., Felestine Square,Ahmadiieh Clinic, Tehran, Iran

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spm@tums.ac.ir

Web page address

<https://spm.tums.ac.ir/contact-us.html>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Jila Naseri

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Position

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Specialist

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Person responsible for updating data

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dr.mtabarraai@yahoo.com

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 more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not 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

Study protocol and statistics analysis map are published.

Trial report is delivered to the university and is not
published in a journal.

When the data will become available and for how long

It depends on the considered journal rules.

To whom data/document is available

Students and scientists who are interested.

Under which criteria data/document could be used

The trial results could be used for review articles and
meta analyses. The journal rules define the access
conditions.

From where data/document is obtainable

Published article and thesis accessible in the university.

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

Access to article depends on the journal rules and access
to thesis file is possible once asking the librarian.

Comments