Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 8897 4535

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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 psychologic 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 committe

Street address

sixth floor, Ghods st., Keshavarz Bulvard

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 questionaire

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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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 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