

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of efficacy of Pimpinella anisum L. topical oil on migraine headache

Protocol summary

Study aim

Evaluation of efficacy of Pimpinella anisum L. topical oil on migraine headache

Design

Two groups of interventional and control groups, which were given as drug and placebo, were randomized with double-blind clinical trial including 50 patients

Settings and conduct

Patients referring to the neurologist at Imam Reza and Shahid Faghihi clinics are referred to the researcher after the diagnosis and examination of the conditions for entry into the study. The researcher give the patient their medications, which is already coded by a pharmacist after the preparation, and medications and placebo cans are the same so that the researcher and the patient are not aware of the medication. After 6 weeks of drug consumption, the drug codes and patient records will be provided to the consultant for analysis.

Participants/Inclusion and exclusion criteria

Entry criteria: age between 18-65 ;at least 2 episodes in 3 months Criteria of failure to enter: pregnancy ; other neurological disorder ; cardiac diseases

Intervention groups

The two intervention and control groups that received the Anisone Cream Intervention Group (7%) and the placebo or non-anise extract cream were used for 6 weeks during the onset of a migraine attack, so that the patient should massage 2cc of the cream in bilateral temporal area on migraine attack

Main outcome variables

The frequency of headaches, the average duration of each headache, the average severity of each headache, the amount of consumption of analgesics

General information

Reason for update

Acronym

تأثیر انیسون بر میگرن

IRCT registration information

IRCT registration number: **IRCT20140108016143N2**

Registration date: **2018-07-27, 1397/05/05**

Registration timing: **retrospective**

Last update: **2018-07-27, 1397/05/05**

Update count: **0**

Registration date

2018-07-27, 1397/05/05

Registrant information

Name

Seyed Hamdollah Mosavat

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 7589

Email address

mosavath@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-07-23, 1396/05/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

empty

Scientific title

Evaluation of efficacy of Pimpinella anisum L. topical oil on migraine headache

Public title

animum effect on migrane headache

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18-65 Migraine Having at least two migraine attacks per month over the past three months

Exclusion criteria:

pregnancy, lactation any other neurological disorder known allergy to anise and/or related products

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Actual sample size reached: **37**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization by 4numbered blocks included 2 intervention patient and 2 control patient

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo are coded and given to patients in the same container, so that neither clinical care nor patient information is available on how to distribute it

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

-

Approval date

2017-07-12, 1396/04/21

Ethics committee reference number

IR.SUMS.MED.REC.1396.55

Health conditions studied**1****Description of health condition studied**

migrane headache

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes**1****Description**

Frequency of headache

Timepoint

week 0,3,6

Method of measurement

The patient records daily headaches

2**Description**

quality of life

Timepoint

week 0 , 3 ,6

Method of measurement

headache impact test-6 (HIT-6) questionnaire

3**Description**

total analgesic consumption

Timepoint

week 0,3,6

Method of measurement

The number of the medication in each interval is recorded on a daily basis by the patient

4**Description**

headache duration

Timepoint

week 0 , 3 ,6

Method of measurement

The patient records daily headaches duration

5**Description**

headache severity

Timepoint

week 0 , 3 ,6

Method of measurement

The patient records daily headaches severity from 0 to 10

+98 71 3235 1087

Email
amin0moayed@gmail.com

Secondary outcomes

1

Description

Any observed adverse event

Timepoint

Sixth week after intervention

Method of measurement

self reporting of patients

Intervention groups

1

Description

Intervention group: The intervention group is given anise cream 7%, which is an anion blend of the extract and cold cream base and prepared as cream for 7%. During the onset of a headache, the patient consumes 2 cc of it in the temporal region. It is allowed to use other analgesics if it does not resolve up to half an hour later. During the course of a 6-month period, the patient's routine drugs such as neurotriptilin, Depakin, and etc will not be discontinued.

Category

Treatment - Drugs

2

Description

Control group: This group contains only cold cream base. During the onset of a headache, the patient experiences 2 cc of it in the temporal region. It is allowed to use other analgesics if it does not resolve up to half an hour later. During the course of a 6-month period, the patient's routine drugs such as neurotriptilin, Depakin, and ... will not be discontinued.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi clinic

Full name of responsible person

Amin Moayedfard

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

2

Recruitment center

Name of recruitment center

Imam Reza clinic

Full name of responsible person

Amin Moayedfard

Street address

Namazi square

City

Shiraz

Province

Fars

Postal code

-

Phone

+98 71 3212 7009

Email

amin0moayed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

71356-44144

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Amin Moayedfard

Position

student of medical science

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Zand

City

Shiraz

Province

Fars

Postal code

-

Phone

+98 71 1234 8550

Email

amin0moayed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr seyed hamdollah mosavat

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

zand

City

shiraz

Province

Fars

Postal code

7135717344

Phone

+98 71 1234 8550

Email

mosavath@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Amin Moayedfard

Position

MD, Candidate of general practition

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

zand st

City

Shiraz

Province

Fars

Postal code

-7135717344

Phone

+98 71 3233 7589

Email

amin0moayed@gmail.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

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

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period one year after the print results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any analysis that leads to a new finding

From where data/document is obtainable

Research Center for Traditional Medicine and History of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran.

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

Submit your written request to the Research Center for Traditional Medicine and History of Medicine in person and indicate the reason for using this data.

Comments