Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of Ocimum Basilicium oil on pain and headache in patient who has migraine

Protocol summary

Study aim

Determination of the effect of Basil on the severity of headache and the frequency of recurrence of headache attacks (the number of migraine attacks over a period of six months) in migraine headache patients

Design

The clinical trial has four types of experimental and control group, each of which is 36, is community based and pragmatic, with parallel groups, blind, randomized

Settings and conduct

Diagnosis was performed by a neurologist at a specialized clinic Rahimi Hospital (Khorramabad-Iran). Essential oil extraction method of Basil plant, in the form of water extraction by water distillation. In all groups, routine treatment, which prescribed acetaminophen 325 for all groups, and only Acetaminophen 325, and other groups, were treated with Acetaminophen with different doses of essential oil of the Basal plant. Basil essential oil was prepared with doses of 2,4,6% and was provided to the patient for topical use on the forehead and every eight hours.

Participants/Inclusion and exclusion criteria

The study population of men and women with migraine headache referring to the Neurology Clinic of Rahimi Hospital (Khorramabad-Iran). In the period from the beginning of the second half of 2013 for a year The upper age limit of 18 years

Intervention groups

Three groups of 36 patients in the experimental group received doses of 2, 4 and 6% of Basilicum and one group of 36, as the control group with 250 doses of Acetaminophen, with the composition of essential oil without the Basilic acid substance in the intervention groups. The experimental group was visited at the specified time intervals (second week, fourth week, second month, third month) by referring to the neurologist and according to designed questionnaires, the relapse rate and headache severity were measured.

Main outcome variables

Severity of pain and number of migraine attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130825014472N3**
Registration date: **2018-07-31, 1397/05/09**
Registration timing: **retrospective**

Last update: **2018-07-31, 1397/05/09**
Update count: **0**

Registration date

2018-07-31, 1397/05/09

Registrant information

Name

Parviz Bahrami

Name of organization / entity

Raziherbal Medicine Center

Country

Iran (Islamic Republic of)

Phone

+98 66 1320 0103

Email address

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Recruitment status

Recruitment complete

Funding source

Raziherbal Medicine Center

Expected recruitment start date

2013-10-12, 1392/07/20

Expected recruitment end date

2014-11-11, 1393/08/20

Actual recruitment start date

2013-12-06, 1392/09/15

Actual recruitment end date

2015-12-30, 1394/10/09

Trial completion date

empty

Scientific title

The effect of Ocimum Basilicium oil on pain and headache in patient who has migraine

Public title

The effect of Ocimum Basilicium on cure Migraine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The study population of men and women with migraine headache referring to the Rahimi hospital clinic (Khorramabad-Iran) In the period from the beginning of the second half of 2013 for a year The upper age limit of 18 years

Exclusion criteria:

Patients who have consumed oral medications - other topical medications during the past 1 month

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **146**

Actual sample size reached: **145**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will achieve with using sample block method.The studied units will be assigned to the four groups according to the criteria for inclusion in the study and available on the basis of randomized blocking. The entry of individuals to each of the groups will be done in the order of the number of selected blocks and will be done using the layout inside the block.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Considering that one of the response variables (severity of pain) is highly dependent on the induction effects, the study is a three-point study. Also, to eliminate the effects of induction, an ophthalmic drug was used in the control group. In case of using the patient with other drugs, the patient was asked to complete the list of all used medications in the relevant form. To evaluate the outcome of the safety organization, no information was given on the dosage of medications and the expected results, so that the conditions could be genuinely evaluated.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Kamalvand

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2013-11-22, 1392/09/01

Ethics committee reference number

200/96196

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

Severe headache

Timepoint

Before and after engaging in the second and fourth week , the second month, third month and sixth month

Method of measurement

VAS scale, Questionnaire bak, Examination physice

2

Description

Relapse

Timepoint

Before and after engaging the second and fourth week , the second month, third month and sixth month

Method of measurement

Questionnaire bak, Examination physice

Secondary outcomes

1

Description
Inside effect
Timepoint
Control in the secondand fourth week, second, third and sixthmonths
Method of measurement
According to condition and observable clinical trait of patient

Intervention groups

1

Description
Intervention: Ocimum Basilicum essential oil applied locally to the forehead of the patient, every eight hours, with doses of 2,4,6 for 6 months.
Category
Treatment - Drugs

2

Description
Control group: To preparation the drug, using liquid paraffin solvent and the control group is given paraffin without ocimum basilicum 's oil .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr bahrami`s office.
Full name of responsible person
Parviz Bahrami
Street address
Crossroad bank
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2

Recruitment center
Name of recruitment center
Rahimi Hospital Clinic
Full name of responsible person
Mahdieh Ahmadifard
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Field of 22 Bahman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Morovat Taheri Kalani
Street address
The end of Razi street, 60 metric
City
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6813833946
Phone
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Science & technology park
Full name of responsible person
Mahdieh Ahmadifard
Position
Expert

Latest degree
Master
Other areas of specialty/work
Others
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Position
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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
Not applicable
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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available