Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy and side effects of topical rose oil in the treatment of acute migraine headache

Protocol summary

Summary

In this study, we try to examine efficacy of this plant as topical analgesic on the acute migraine attack. Method and materials: This is a Randomized, Placebo-controlled, Crossed-over Study conducted in 40 patients of the neurology Clinic of Emam Reza and Shahid Faghihi hospital, affiliated with Shiraz University of Medical Sciences,Shiraz/ Iran. The study for each patient for four attacks and a total of 120 attacks were examined.the 20 patient for initial two migraine attacks were treated with rose oil and the second two attacks with the placebo.the other 20 patient managed in the opposite order receiving the placebo for the first two attacks and rose oil for the second two attacks of migraine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511257297N2**
Registration date: **2015-12-12, 1394/09/21**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name
Mojtaba Heydari
Name of organization / entity
Shiraz university of medical science
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Recruitment status

Not enough for processing

Funding source

shiraz university of medical science

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and side effects of topical rose oil in the treatment of acute migraine headache

Public title

topical rose oil in the patients with migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:patients with migraine headache based on 3th edition of IHS and ICHD criteria, age over 18 years, having at least 2 migraine headache every months. exclusion criteria:sensitivity to rose flowersl, pregnancy, don't sign informative testimonial, getting worse headache intensity with olphactory stimulation of drug or placebo, new diagnosed case with indication of preventive therapy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features
basic demographic of patients, basic demographic of their headache, pain intensity of patients based on VAS before use and till 24hr after use of drug or placebo, intensity of their headache features such as nausea/vomiting,get away of light(photophobia), get away of sound with use of drug or placebo for 2hr, pain intensity in cold and hot temperament patients after use the drug or placebo

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Science
Street address
Shiraz, Zand street, shiraz university of medical sciense
City
Shiraz
Postal code
7134845794
Approval date
2015-08-08, 1394/05/17
Ethics committee reference number
IR.SUMS.med.REC.1394.45

Health conditions studied

1

Description of health condition studied
migraine headache
ICD-10 code
G43.0 and
ICD-10 code description
migraine without aura(common migraine) and migraine with aura(classical migraine)

Primary outcomes

1

Description
pain intensity
Timepoint
0 min, 15min, 30 min, 45 min, 60 min, 90 min, 120 min, 6 hr, 12 hr, 24hr
Method of measurement
visual analogue scale of pain(VAS)

2

Description
photophobia
Timepoint
0 min, 30 min, 2hr
Method of measurement
visual analogue scale of pain(VAS)

3

Description
nausea/vomiting
Timepoint
0 min, 30 min, 2hr
Method of measurement
visual analogue scale of pain(VAS)

4

Description
get away of sound
Timepoint
0 min, 30 min, 2hr
Method of measurement
visual analogue scale of pain(VAS)

Secondary outcomes

1

Description
Any adverse reaction to the intervention
Timepoint
0min, 15min, 30min,45min, 60min, 90min, 120min, 6hr, 12hr, 24hr
Method of measurement
visual analogue scale of pain(VAS)

Intervention groups

1

Description
essential rose oil as a drug, 7cc, almost 2cc in every attack used topical in temporal and frontal area, interval of attacks was minimum 1 week as washout period
Category
Treatment - Drugs

2

Description

Liquid paraffin as a placebo, 7cc, almost 2cc in every attack used topical in temporal and frontal area, interval of attacks was minimum 1 week as washout period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

neurology clinic of Namazi hospital(Emam Reza clinic)

Full name of responsible person

Maria Niazi(general practitioner)

Street address

Shiraz,Namazi square,Emam Reza clinic/Yasuj,Bahonar Blvd, 3th avenue, No 33

City

Yasuj

2

Recruitment center

Name of recruitment center

Neurology clinic of Shahid Faghihi hospital

Full name of responsible person

Maria Niazi(general practitioner)

Street address

Shiraz,Zand Street, Faghihi hospital/Yasuj,Bahonar Blvd, 3th avenue, No 33

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

shiraz university of medical science

Full name of responsible person

Abdolhamid Shariat

Street address

Shiraz,zand street, shiraz university of medical science,Vice chancellor for research

City

Shiraz

Grant name

IR.SUMS

Grant code / Reference number

1394.45

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

Yes

Title of funding source

shiraz university of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

shiraz university of medical science

Full name of responsible person

Maria Niazi

Position

general practitioner

Other areas of specialty/work

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Assistant professor of traditional medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty