

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

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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 flowers, pregnancy, don't sign informative testimonial, getting worse headache intensity with olfactory 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 science

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

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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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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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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

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Position

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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