

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of aromatherapy with lavender essential oil on depression and headache disability in migraine patients

Protocol summary

Summary

The aim of this study is to determine the effect of aromatherapy with lavender essential oil on depression and headache disability in migraine patients. This randomization clinical trial study are conducted on 80 migraine patients referred to Tooba clinic. Patients Including major criteria: being over 18 years; alertness and ability to communicate; at least 6 months of having migraine headache; having good sense of smell according to the neurological examination; having criterias of migraine without aura according to the classification of the International headache society (IHS); don't using psychiatric drugs specially anti-depressants drugs; under prophylactic treatment by Depakin 500 produced by Sanofi aventis one time every night. Patients eligibility major criteria: pregnancy or decision to pregnancy; record of allergies; incidence of allergy during intervention. At first, Beck depression scale and headache disability scale will be used for the assessment of depression and headache disability. Experimental group: experimental group will be exposed to the inhalation of lavender essence produced by Barij certified pharmaceutical company with quality standards of ISO 9001 and ISO/IEC 17025 at a concentration of 100 percent for 4 week. A cotton ball soaked with 2 drops of lavender essential oil will be put on the collar of patients and will be asked to breath normally for 15 minutes three times a week (even days). Control group : Control group will be exposed to the inhalation of liquid paraffin produced by Kimiagar Toos. A cotton ball soaked with 2 drops of liquid paraffin as a placebo will be put on the collar of patients and will be asked to breath normally for 15 minutes three times a week (even days) until 4 weeks. Depression and headache disability scales will be complete in the end of 2nd and 4th week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608117494N22**

Registration date: **2017-08-22, 1396/05/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-22, 1396/05/31

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7551

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Mazandaran University of Medical Sciences.

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with lavender essential oil on

depression and headache disability in migraine patients

Public title
Effect of lavender on depression and headache disability in migraine patients

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria: being over 18 years; alertness and ability to communicate; at least 6 months of having migraine headache; don't have a cold; don't using perfume before and during the intervention; having good sense of smell according to the neurological examination; having criteria of migraine without aura according to the classification of International Headache Society (IHS); don't using psychiatric drugs specially anti-depressants drugs; Under prophylactic treatment by Depakin 500 produced by Sanofi Aventis one time every night, under treatment of acute phase of headache by NSAID at the incidence of headache. Exclusion criteria: pregnancy or decision to pregnancy; record of allergies; Acute respiratory disease; addiction; allergy during intervention.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran university of medical science

Street address

Moalem street , Moalem Square

City

Sari

Postal code

Approval date

2016-12-12, 1395/09/22

Ethics committee reference number

IR.MAZUMS.REC.95.2439

Health conditions studied

1

Description of health condition studied

migraine patients

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura[common migraine]

Primary outcomes

1

Description

Depression

Timepoint

Before intervention first week, two weeks after intervention and four weeks after intervention

Method of measurement

Beck Depression scale

2

Description

Headache disability

Timepoint

Before intervention first week, two weeks after intervention and four weeks after intervention

Method of measurement

Headache disability inventory

Secondary outcomes

1

Description

Allergic to lavender

Timepoint

During four weeks of intervention

Method of measurement

Questions from patients

Intervention groups

1

Description

Control group: patients will be exposed to the inhalation of liquid paraffin produced by Kimiagar Toos Company. In experimental group a ball soaked with 2 drops of liquid paraffin will be attached to the collar of patient three times a week (even days: Saturday, Monday and Wednesday) for four weeks and will be asked to breathe normally every time for 15 minutes.

Category

Treatment - Drugs

2**Description**

Experimental group will be exposed to the inhalation of lavender essence produced by Barij certified pharmaceutical company with quality standards of ISO 9001 and ISO/IEC 17025. Lavender essence is produced from fresh flowering parts of the plant which contains Linalool, Linalool acetate, Caffeic acid and Tannins. In experimental group a cotton ball soaked with 2 drops of lavender essential oil with concentration of 100 percent will be attach to collar of patient three times a week (even days: Saturday, Monday and Wednesday) for 4 weeks and will be asked to breath normally every time for 15 minutes.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tooba clinic (Baghban)

Full name of responsible person

Azar jafari koulaee, Fatemeh Khenarinezhad

Street address**City**

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmad Ali Enayati

Street address

Moalem street, Moalem square

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research Mazandaran University of Medical Sciences

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**

Mazandaran University of Medical science

Full name of responsible person

Azar jafari Koulaee

Position

Nursing student

Other areas of specialty/work**Street address**Vesal street, School of nursing and midwifery
Mazandaran University of Medical sciences**City**

Sari

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Mazandaran University of Medical sciences

Full name of responsible person

Dr Masoumeh Bagheri-Nesami

Position

Associate Professor

Other areas of specialty/work**Street address**Sari, Vessal street, School of nursing and midwifery
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Web page address**Person responsible for updating data****Contact****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