Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of aromatic necklace containing Peppermint and Lavender essential oils versus necklace without essence on the clinical symptoms of patients with migraine: a single-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of aromatic necklace containing Peppermint and Lavender essential oils versus necklace without essence on the clinical symptoms of patients with migraine

Design
This is a single-blind randomized clinical trial with control group, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct
This study will be performed in the Sina Hospital in Hamadan city on 72 eligible patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 55 years; Affected with migraine; Exclusion criteria: Pregnancy; Sensitivity to peppermint and lavender

Intervention groups
Intervention group: Routine treatment of migraine in addition to using a necklace containing one ml of a mixture of peppermint and lavender essential oil (which comes out of the grooves as a fragrance) for 15 minutes during a headache for a month Control group: Routine treatment of migraine in addition to using a necklace without essence for 15 minutes during a headache for a month

Main outcome variables
Primary outcome: The severity of headache

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20120215009014N423**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-18, 1401/01/29**
Update count: **0**

Registration date
2022-04-18, 1401/01/29

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-04, 1401/01/15
Expected recruitment end date
2022-05-21, 1401/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of aromatic necklace containing Peppermint and

Lavender essential oils versus necklace without essence on the clinical symptoms of patients with migraine: a single-blind randomized clinical trial

Public title
Effect of aromatic necklace containing Peppermint and Lavender essential oils versus necklace without essence on the clinical symptoms of patients with migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 55 years; Affected with migraine;
Exclusion criteria:
Pregnancy; Sensitivity to peppermint and lavender
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as single-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2020-05-09, 1399/02/20
Ethics committee reference number
IR.UMSHA.REC.1399.131

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
The severity of headache
Timepoint
Before the intervention and one month after that
Method of measurement
Using Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment of migraine in addition to using a necklace containing one ml of a mixture of peppermint and lavender essential oil (which comes out of the grooves as a fragrance) for 15 minutes during a headache for a month
Category
Treatment - Devices

2

Description
Control group: Routine treatment of migraine in addition to using a necklace without essence for 15 minutes during a headache for a month
Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital in Hamadan city
Full name of responsible person
Shima Bayat
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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Position
Student of Pharmacy
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
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