Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Phytochemical and clinical effect of a herbal medicine containing mint, rosemary, lavender, and clove compared to placebo on the prevention and control of migraine symptoms: a triple-blind randomized clinical trial

Protocol summary

Study aim

To assess the phytochemical and clinical effect of a herbal medicine containing mint, rosemary, lavender, and clove compared to placebo on the prevention and control of migraine symptoms

Design

This is a Phase III triple-blind randomized clinical trial with a control group with parallel groups, in which 155 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the School of Pharmacy in Hamadan city, involving 155 eligible patients with migraine. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be triple-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 55 years, Diagnosis of migraine, Experience of at least 4 migraine attacks in the past three months, Exclusion criteria: Use of similar herbal medicines in the past 2 months, Pregnancy or breastfeeding, Presence of other neurological disorders such as epilepsy or multiple sclerosis, Use of antidepressant or anticonvulsant medications in the past 2 months

Intervention groups

Intervention group 1: Routine treatment plus herbal medicine containing mint applied Intervention group 2: Routine treatment plus herbal medicine containing rosemary applied Intervention group 3: Routine treatment plus herbal medicine containing lavender applied Intervention group 4: Routine treatment plus combined herbal medicine containing clove Control group: Routine treatment plus placebo without any herbal ingredient

Main outcome variables

Primary outcome: Number of migraine attacks Headache severity Mean duration of migraine attacks Secondary outcome: Improvement in sleep quality Amount of analgesic medication use Mean mood and anxiety score before Mean patient satisfaction score before

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N611**
Registration date: **2026-05-19, 1405/02/29**
Registration timing: **prospective**

Last update: **2026-05-19, 1405/02/29**
Update count: **0**

Registration date

2026-05-19, 1405/02/29

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phytochemical and clinical effect of a herbal medicine containing mint, rosemary, lavender, and clove compared to placebo on the prevention and control of migraine symptoms: a triple-blind randomized clinical trial

Public title

Phytochemical and clinical effect of a herbal medicine containing mint, rosemary, lavender, and clove compared to placebo on the prevention and control of migraine symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 55 years, Diagnosis of migraine, Experience of at least 4 migraine attacks in the past three months,

Exclusion criteria:

Use of similar herbal medicines in the past 2 months, Pregnancy or breastfeeding, Presence of other neurological disorders such as epilepsy or multiple sclerosis, Use of antidepressant or anticonvulsant medications in the past 2 months

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **155**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients into intervention and control groups is done by lottery. For this purpose, we prepare five cards: on four cards we write the names of the interventions, and on one card we write the name of the placebo. Then, upon each patient's arrival, we randomly draw one card without replacement and assign the patient to either the intervention or the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drugs will be administered in coded envelopes. Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. The distributer of the medicines will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a triple-blind study.

Placebo

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, Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2026-05-09, 1405/02/19

Ethics committee reference number

IR.UMSHA.REC.1405.106

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Number of migraine attacks

Timepoint

Before intervention and one month later

Method of measurement

By medical history

2

Description
Headache severity
Timepoint
Before intervention and one month later
Method of measurement
Using the Visual Analogue Scale (VAS)

3

Description
Mean duration of migraine attacks
Timepoint
Before intervention and one month later
Method of measurement
By medical history

Secondary outcomes

1

Description
Improvement in sleep quality
Timepoint
Before intervention and one month later
Method of measurement
Using the Pittsburgh Sleep Quality Index (PSQI)

2

Description
Amount of analgesic medication use
Timepoint
before intervention and one month later
Method of measurement
By medical history

3

Description
Mean mood and anxiety score
Timepoint
before intervention and one month later
Method of measurement
Using the Depression Anxiety Stress Scales - 21 (DASS-21)

4

Description
Mean patient satisfaction score
Timepoint
Before intervention and one month later
Method of measurement
Using a researcher-designed questionnaire

Intervention groups

1

Description
Intervention group 1: Routine treatment plus herbal medicine containing mint applied as local massage on the temples, neck, forehead, and behind the ears three times per week for one month.
Category
Treatment - Drugs

2

Description
Intervention group 2: Routine treatment plus herbal medicine containing rosemary applied as local massage on the temples, neck, forehead, and behind the ears three times per week for one month.
Category
Treatment - Drugs

3

Description
Intervention group 3: Routine treatment plus herbal medicine containing lavender applied as local massage on the temples, neck, forehead, and behind the ears three times per week for one month.
Category
Treatment - Drugs

4

Description
Intervention group 4: Routine treatment plus combined herbal medicine containing clove applied as local massage on the temples, neck, forehead, and behind the ears three times per week for one month.
Category
Treatment - Drugs

5

Description
Control group: Routine treatment plus placebo without any herbal ingredient applied as local massage on the temples, neck, forehead, and behind the ears three times per week for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Pharmacy in Hamadan
Full name of responsible person
Dorsa Mahdizade
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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
Dorsa Mahdizade

Position
Student of Pharmacology

Latest degree
Medical doctor

Other areas of specialty/work
Medical 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