Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial for comparing the effect of aromatherapy with Lavender essential oil with Acetaminophen tablet 325 mg in treatment of headache in patient receiving Nitroglycerine infusion.

Protocol summary

Summary

In this clinical trial study with aim to compare the effect of aromatherapy with Lavender essential oil with Acetaminophen tablet 325 mg in treatment of headache in patient receiving Nitroglycerine infusion, 135 patients receiving Nitroglycerine infusion will be selected with available sampling method and then randomly allocated in tree groups (Lavender essential oil, Acetaminophen tablet and placebo). Randomization will be performed by choosing sealed envelopes containing different treatment protocols. Inclusion criteria: Age between 18 to 65; Written consent to participate in research; The ability to speak Persian; No record of Allergic Rhinitis; No record of respiratory problems; Not using analgesic drugs before admission; Having no headache; No diagnosed psychiatric disorder; Being aware of time, place and subject; No record of olfactory dysfunction; No addiction; Having a maximum score of 31 based on Spielberger State-anxiety questionnaires score. Exclusion criteria: Patient unwillingness to participate in the research; Use analgesics drugs; Sensitivity to lavender aroma. The intensity and quality of headache will be measured based on visual analogue scale and modify short form McGill pain questionnaire, Before and 15, 30 and 60 minutes after the intervention. Once the headache is started, in the Lavender essential oil group, subjects will inhale Lavender essential oil by smeared with a cotton filled by 3 drops of Lavender essential oil for 30 minutes, in the Acetaminophen tablet group, one 325 mg tablet will be used orally and in the placebo group, liquid paraffin will be used for the same time period

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015033121569N1**
Registration date: **2015-07-15, 1394/04/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-07-15, 1394/04/24

Registrant information

Name

Ehsan Eshghi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3879 5031

Email address

eshghie901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences.

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial for comparing the effect of aromatherapy

with Lavender essential oil with Acetaminophen tablet 325 mg in treatment of headache in patient receiving Nitroglycerine infusion.

Public title
The effect of Lavender essential oil in treatment of headache.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age between 18 to 65; Written consent to participate in research; The ability to speak Persian; No record of Allergic Rhinitis; No record of respiratory problems; Not using analgesic drugs before admission; Having no headache; No diagnosed psychiatric disorder; Being aware of time, place and subject; No record of olfactory dysfunction; No addiction; Having a maximum score of 31 based on Spielberger State-anxiety questionnaires score. Exclusion criteria: Patient unwillingness to participate in the research; Use analgesics drugs; Sensitivity to lavender aroma.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization will be performed by choosing sealed envelopes containing different treatment protocols.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in research of Mashhad University Of Medical Science
Street address
Research ethics committee, Ghorayshi building, Daneshgah avenue, Mashhad, Iran
City
Mashhad
Postal code
9177899191
Approval date
2014-10-01, 1393/07/09
Ethics committee reference number
930236

Health conditions studied

1

Description of health condition studied
headache
ICD-10 code
G44.1
ICD-10 code description
Vascular headache, not elsewhere classified

Primary outcomes

1

Description
Headache Severity
Timepoint
Before and 15,30 and 60 minutes after intervention
Method of measurement
Visual Analog Scale

2

Description
Headache Quality
Timepoint
Before and 15,30 and 60 minutes after intervention
Method of measurement
Modify Short Form McGill Pain Questionnaire

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
3 drops of Lavender Essential Oil is inhaled for 30 minutes as soon as headache beginning.
Category
Treatment - Other

2

Description
One 325 mg Acetaminophen tablet is used orally as soon as headache beginning.
Category
Treatment - Drugs

3

Description
3 drops of liquid paraffin is inhaled for 30 minutes as soon as headache beginning.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiac emergency department of Mashhad Farabi hospital.
Full name of responsible person
Ehsan Eshghi
Street address
Farabi hospital, Kowsar boulevard, Vakilabad boulevard, Mashhad, Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Saeed Eslami
Street address
Ghorayshi building, Daneshghah avenue, Mashhad, Iran
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Mashhad
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, Mashhad 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

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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