

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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, Daneshgah avenue, Mashhad, Iran

City

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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ehsan Eshghi

Position

MS Student in critical care Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery

City

Mashhad

Postal code

Phone

+98 51 3525 1751

Fax

Email

eshghie901@mums.ac.ir; eh.san36@yahoo.com; eh.san36@mihanmail.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Gholam Hossein Zarifnejad

Position

MSc Nursing, Faculty Member of Mashhad University of Medical Sciences

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Doktora cross, Mashhad, Iran

City

Mashhad

Postal code

Phone

+98 51 3859 1511

Fax

Email

zarifnejadgh@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ehsan Eshghi

Position

MS Student in critical care Nursing

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Doktora cross,
Mashhad, Iran

City

Mashhad

Postal code**Phone**

+98 51 3525 1751

Fax**Email**

eshghie901@mums.ac.ir; eh.san36@yahoo.com;
eh.san36@mihanmail.ir

Web page address**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