

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of aromatherapy with lavender oil on post dura puncture headache

Protocol summary

2017-05-29, 1396/03/08

Summary

Objective: comparing the effect of aromatherapy with lavender oil and liquid paraffin on post dura puncture headache in patients undergoing spinal anesthesia
Design: double blind randomized clinical trial
Randomization: Subjects will allocate to two equal groups of control and intervention using block randomization method. Participants including major eligibility criteria: this study will conduct on 50 patients with post dura puncture headache following spinal anesthesia refer to Qom Shahid Behashti and Kamkar-Arabnia Hospital. Main inclusion criteria include having post dura puncture headache following spinal anesthesia; having no emergency conditions; lack of being in delivery or near the delivery period (until 45 days after the delivery); lack of seizures, history of migraine, tensional and other kinds of headaches, infection diseases (such as sinusitis or meningitis), intrathecal disorders, sever heart diseases and diabetes and main exclusion criteria include unwillingness for study follow-up and having nausea and vomiting or other complications due to severe headache. Main outcome: headache Intervention: Subjects in intervention group will inhale 3 drops of lavender oil 2% poured on upper lip during 15 minutes. Subjects in control group will inhale 3 drops of placebo (liquid paraffin) poured on upper lip during 15 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051617468N3**

Registration date: **2017-05-29, 1396/03/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Meysam Hoseini Amiri

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qom University of Medical Sciences

Expected recruitment start date

2017-06-05, 1396/03/15

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with lavender oil on post dura puncture headache

Public title

Compassion the effect of aromatherapy with lavender oil and liquid paraffin on post dura puncture headache in patients undergoing spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having informed written consent for research participation; age of 18-60 years old; having complete consciousness; having no emergency conditions; having communication and speaking abilities; lack of being in delivery or near the delivery period (until 45 days after the delivery); having post dura puncture headache following spinal anesthesia; lack of seizures, history of migraine, tensional and other kinds of headaches, infection diseases (such as sinusitis or meningitis), intrathecal disorders, severe heart diseases and diabetes. Exclusion criteria: Unwillingness for study follow-up; having nausea and vomiting or other complications due to severe headache.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Subjects will allocate to two equal groups of control and intervention using block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Researches of Qom
University of Medical Sciences

Street address

Vice chancellor for research of Qom University of
Medical Sciences, Safashar road, Qom, Iran

City

Qom

Postal code

Approval date

2017-05-02, 1396/02/12

Ethics committee reference number

IR.MUQ.REC.1396.16

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.8

ICD-10 code description

Other specified headache syndromes

Primary outcomes

1

Description

Post dura puncture headache

Timepoint

Before intervention and immediately, 30, 60, 90, and 120
minutes after the intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Quality of headache

Timepoint

Immediately after intervention

Method of measurement

Modified McGill quality of pain questionnaire

Intervention groups

1

Description

Subjects in control group will inhale 3 drops of placebo
(liquid paraffin) poured on upper lip during 15 minutes.

Category

Prevention

2

Description

Subjects in intervention group will inhale 3 drops of
lavender oil 2% poured on upper lip during 15 minutes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Kamkar-Arabnia Hospital

Full name of responsible person

Meysam Hoseini Amiri

Street address

Qom Kamkar-Arabnia Hospital, Bjak road, Qom

City

Qom

2**Recruitment center****Name of recruitment center**

Qom Shahid Behashti Hospital

Full name of responsible person

Meysam Hoseini Amiri

Street addressQom Shahid Behashti Hospital, Shahid Behashti road,
Qom**City**

Qom

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research, Qom University of
Medical Sciences**Full name of responsible person**

Hossein Saghaei

Street addressVice chancellor for research of Qom University of
Medical Sciences, Safashar road, Qom**City**

Qom

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

Yes

Title of funding sourceVice chancellor for research, Qom 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**

Qom University of Medical Sciences

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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*