

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Inhalation of Mint Oil on Vital Signs and O2 Saturation in neurosurgery Patient Hospitalized in Intensive Care Unit

Protocol summary

Study aim

Effect of Inhalation of Mint Oil on Vital Signs and O2 Saturation in neurosurgery Patient Hospitalized in Intensive Care Unit

Design

The study will be performed as a single-blind randomized clinical trial (researcher) in the intensive care unit of Qom Health Donors Hospital. Participants will be 80 neurosurgery patients who will be randomly assigned to two intervention and control groups.

Settings and conduct

The present study will be performed in the intensive care unit of Qom Health Donors Hospital. Participants will be 80 neurosurgery patients. Vital signs and participants' blood oxygen saturation percentage will be recorded and compared immediately before the intervention, 15, 30 minutes, and 1, 3, and 6 hours after the intervention. Two identical jars are prepared from peppermint extract and distilled water with a dye in a sterile manner and only labels "A" and "B" are placed on them. Blinding will also be used in statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age over 18 years and less than 50 years 2- No history of allergy to a particular substance 3- Awareness level above 13 according to Glasgow criteria 4- No history of addiction 5 - No underlying disease (diabetes, hypertension, chronic heart failure, respiratory failure and renal failure) 6- No endotracheal tube or 24 hours at the beginning of its removal 7- Stability of vital signs at least 12 hours before the intervention

Intervention groups

In the intervention group, 0.2 ml of 10% peppermint extract with 10 ml of distilled water will be nebulized through the nebulizer mask for 15 minutes with oxygen and in the control group, 0.2 ml of green colored distilled water with 10 ml of distilled water will be nebulized through the nebulizer mask for 15 minutes with oxygen.

Main outcome variables

vital signs (blood pressure, heart rate and respiration)

and blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050189N1**

Registration date: **2021-05-13, 1400/02/23**

Registration timing: **prospective**

Last update: **2021-05-13, 1400/02/23**

Update count: **0**

Registration date

2021-05-13, 1400/02/23

Registrant information

Name

Raziyeh Ghafouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 4520

Email address

ghafouri@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-16, 1400/02/26

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Inhalation of Mint Oil on Vital Signs and O2 Saturation in neurosurgery Patient Hospitalized in Intensive Care Unit

Public title

Effect of Inhalation of Mint Oil on Vital Signs and O2 Saturation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years and under 50 years No history of allergy to a particular substance- Awareness level above 13 according to Glasgow criteria No history of addiction No underlying disease (diabetes, high blood pressure, chronic heart failure, respiratory failure and kidney failure)- No endotracheal tube or 24 hours after extubation Stability of vital signs at least 12 hours before the extubation

Exclusion criteria:

Any sudden change in vital signs and general condition during the intervention that is a sign of intolerance to aromatherapy. Any change in the patient's breathing pattern during the intervention Change in the patient's medication during the intervention up to 6 hours after the intervention Complications after surgery such as severe pain, active bleeding, or infection

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization by Random allocation rule will be used. Random allocation will be done with white and black cards. For allocation concealment, Sequentially numbered, opaque envelopes, sealed envelopes will be used. Before the intervention, 40 white cards and 40 black cards are placed in an envelope and taken out, respectively. The order of the removed cards from 1 to 80 is placed on the special envelopes for sampling. With the order of the samples, a special envelope is opened and it is placed in group A or B based on the color of the patient's card. If the card taken out of the envelope is white, the patient is in group A, and if the card is black, the patient is in group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Two identical medicine bottles are prepared from

peppermint extract and a medicine bottle containing distilled water with a colored substance in a sterile form. Placed on them. For aromatherapy in group A, a medicine glass labeled "A" will be used and in group B, a medicine glass labeled "B" will be used. Also, in statistical analysis, blinding will be used, in which the statistical consultant will be unaware of the two groups of intervention and control, and the two groups will be introduced to him as groups A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medical Sciences (Biomedic

Street address

Vali-Asr Avenue, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Opposite to Rajae Heart Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.014

Health conditions studied

1

Description of health condition studied

neurosurgery Patient Hospitalized in Intensive Care Unit

ICD-10 code

S06.4X

ICD-10 code description

Epidural hemorrhage

2

Description of health condition studied

neurosurgery Patient Hospitalized in Intensive Care Unit

ICD-10 code

S06.5X

ICD-10 code description

Traumatic subdural hemorrhage

3

Description of health condition studied

neurosurgery Patient Hospitalized in Intensive Care Unit

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Blood pressure

Timepoint

6 hours after intervention

Method of measurement

blood pressure monitoring

2

Description

O2 Saturation

Timepoint

6 hours after intervention

Method of measurement

pulse oximetry

3

Description

pulse rate

Timepoint

6 hours after intervention

Method of measurement

heart rate monitoring

4

Description

respiratory rate

Timepoint

6 hours after intervention

Method of measurement

respiratory rate monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.2 ml of 10% peppermint extract with 10 ml of distilled water will be nebulized through the nebulizer mask for 15 minutes with oxygen.

Category

Treatment - Other

2

Description

Control Group: 0.2 ml of green distilled water with 10 ml of distilled water will be nebulized through the nebulizer mask for 15 minutes with oxygen.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Health Donors Hospital

Full name of responsible person

Ali Fooladvand

Street address

Qom Health Donors Hospital

City

Ghous

Province

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1996835119

Phone

+98 21 8820 2520

Email

afoolad133@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

shahid beheshti univercity of medical science

Street address

Vali-Asr Avenue, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Opposite to Rajae Heart Hospital, Tehran

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Email

raziieghafouri@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

no thing

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Raziyeh Ghafouri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

After defending the dissertation and publishing the article

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further research

From where data/document is obtainable

By email of the co responder author:

raziehghafouri@gmail.com

What processes are involved for a request to access

data/document

Ask the responsible author in an email. Mention the purpose and location of the research in the email. The co responder author will be answered within two weeks

Comments