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)

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+98 28 3335 4520

Email address
ghafouri@sbmu.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 Rajaee 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
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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
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Vali-Asr Avenue, Cross of Vali-Asr Avenue and Hashemi Rafsanjani (Neiaiesh) Highway, Opposite to Rajaee Heart Hospital, Tehran
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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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