Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Peppermint aromatherapy to prevent nausea and vomiting after strabismus surgery in children: a randomized trial

Protocol summary

Study aim
The effect of "peppermint" aromatherapy on nausea and vomiting after strabismus surgery in children.

Design
A clinical trial with the control group, with parallel groups, Randomization tool: sealed envelope.

Settings and conduct
In this randomized clinical trial, children aged 5-12 years and eligible to study after strabismus surgery and immediately after admission to recovery; the informed consent of their parents was received, they are randomly divided into three groups (using sealed envelopes).

Participants/Inclusion and exclusion criteria
Inclusion criteria: children aged 5 to 12 years and parental consent based on their child's participation in the study. Non-inclusion criteria include a history of respiratory diseases such as asthma, rhinitis, chronic sinusitis, history of analgesics, hypnotics, sedation during the week before surgery, respiratory allergies to essential oils, perfumes, and history of dermatitis in the child.

Intervention groups
The patients are received massage therapy with peppermint oil in the intervention group and distilled water as a placebo in the control group.

Main outcome variables
Occurrence of nausea and vomiting 10, 30, 45, 60, 120, 180 minutes after strabismus surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150731023429N3**
Registration date: **2021-09-19, 1400/06/28**
Registration timing: **registered_while_recruiting**
Last update: **2021-09-19, 1400/06/28**
Update count: **0**

Registration date
2021-09-19, 1400/06/28

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3844 2058
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ebrahimns@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-06, 1400/06/15

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Peppermint aromatherapy to prevent nausea and vomiting after strabismus surgery in children: a randomized trial

Public title
The effect of Peppermint aromatherapy to prevent nausea and vomiting after eye muscle surgery in children: a randomized trial

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
5 to 12-year-old children; candidate for strabismus surgery Parental consent for their children's participation in the study
Exclusion criteria:
History of pediatric respiratory diseases such as asthma, rhinitis, chronic sinusitis The history of using analgesics, hypnotics, and sedatives within one week before surgery. History of dermatitis in children History of respiratory allergies to essential oils, perfumes

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization tool: sealed envelope Randomization will be done as a simple method with the card. The type of intervention is placed in the sealed envelopes. Individuals are listed in order of attendance. After including the study, the envelopes will be shuffling, and each participant is asked to choose an envelope. The number of envelopes is provided depending on the study sample size. Therefore, any selected envelope will not return to the randomization sequence. This type of randomization can lead to the same number of individuals in both groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Imam Reza Hospital,Ibn Sina Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2016-10-05, 1395/07/14

Ethics committee reference number
IR.MUMS.fm.REC.1395.107

Health conditions studied

1

Description of health condition studied
Aromatherapy and nausea vomiting after strabismus surgery in children

ICD-10 code
H50

ICD-10 code description
Other strabismus

Primary outcomes

1

Description
Postoperative nausea

Timepoint
Nausea at 10, 30, 45, 60, 120, 180 minutes postoperative

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
postoperative vomiting

Timepoint
Vomiting at 10, 30, 45, 60, 120, 180 minutes postoperative

Method of measurement
Postoperative monitoring

Intervention groups

1

Description
Intervention group: Receiving peppermint oil massage. The procedure will be performed by massaging 3 drops of peppermint oil on points LI11 and LI4 of each hand for 10 minutes.

Category
Prevention

2

Description
Control group: Receiving distilled water massage. The procedure will be performed by massaging 3 drops of distilled water on points LI11 and LI4 of each hand for 10 minutes.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Hospital
Full name of responsible person
Soheila Ebrahimnia Milani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vice-Chancellor for Research of Mashhad University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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

2

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Clinical Research Development Unit
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Imam Reza Hospital,Ibn Sina Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Soheila Ebrahimnia Milani
Position
Assistant Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable