

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+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

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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

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

2

Sponsor

Name of organization / entity
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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
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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
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Assistant Professor of Anesthesiology
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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