Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Effect of inhalation aromatherapy with lavender and chamomile essential oils versus acetaminophen on post adenotonsillectomy pain in children: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of inhalation aromatherapy with lavender and chamomile essential oils versus acetaminophen on post adenotonsillectomy pain in children. Design: a triple blind randomized clinical trial. Setting and conduct: The eligible children who are candidate for adenotonsillectomy and will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 5 to 12 years; (b) candidate for adenotonsillectomy. Exclusion criteria: (a) history of allergy; (b) sensitivity to ethers and aromatic compounds; (c) history of asthma; (d) severe bleeding during operation; (e) using analgesic during operation. Intervention group 1: Lavender essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg. Intervention group 2: Chamomile essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg. Intervention group 3: Lavender and chamomile compound essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg. Control group: Distilled water 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg. Primary outcome: Assessing the pain on the operational location every 6 hours for 3 days using visual analog scale. Secondary outcome: (a) assessing nausea and vomiting every 6 hours for 3 days through question from the patient; (b) assessing bleeding form the operational location every 6 hours for 3 days through physical examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506159014N70**
Registration date: **2015-06-18, 1394/03/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-06-18, 1394/03/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-07-01, 1394/04/10

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of inhalation aromatherapy with lavender and chamomile essential oils versus acetaminophen on post adenotonsillectomy pain in children: a triple blind randomized clinical trial

Public title

Effect of inhalation aromatherapy with lavender and chamomile essential oils versus acetaminophen on post adenotonsillectomy pain in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 5 to 12 years; (b) candidate for adenotonsillectomy. Exclusion criteria: (a) history of allergy; (b) sensitivity to ethers and aromatic compounds; (c) history of asthma; (d) severe bleeding during operation; (e) using analgesic during operation.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 12 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

IR.UMSHA.REC.1394.79

Health conditions studied

1

Description of health condition studied

Tonsillitis

ICD-10 code

J35.0

ICD-10 code description

Chronic tonsillitis

Primary outcomes

1

Description

Assessing the pain on the operational location

Timepoint

every 6 hours for 3 days

Method of measurement

using visual analog scale

Secondary outcomes

1

Description

assessing nausea and vomiting

Timepoint

every 6 hours for 3 days

Method of measurement

through question from the patient

2

Description

assessing bleeding form the operational location

Timepoint

every 6 hours for 3 days

Method of measurement

through physical examination

Intervention groups

1

Description
Lavender essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg.
Category
Treatment - Drugs

2

Description
Chamomile essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg
Category
Treatment - Drugs

3

Description
Lavender and chamomile compound essential oils 1%, 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg
Category
Treatment - Drugs

4

Description
Distilled water 3 drops every 6 hours during the first 24 hours and then, every 8 hours for the next 48 hours through inhalation plus oral acetaminophen 10 to 15 mg/kg
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr Mohammad Alipoor
Street address
Besat Hospital, Shahed Square
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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
Besat Hospital
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Person responsible for updating data

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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