

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

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

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

Full name of responsible person

Dr Mohammad Alipoor

Position

ENT Resident

Other areas of specialty/work

Street address

Besat Hospital, Shahed Square

City

Hamadan

Postal code

Phone

+98 81 3364 0030

Fax

Email

dralipour76@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Besat Hospital

Full name of responsible person

Dr Mohammad Saeid Ahmadi

Position

Otolaryngologist

Other areas of specialty/work

Street address

Besat Hospital, Shahed Square

City

Hamadan
Postal code
Phone
+98 81 3364 0030
Fax
Email
ahmadi@umsha.ac.ir
Web page address

6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code

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