Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of aromatherapy with orange essential oil on pain intensity, nausea and vomiting following adenotonsillectomy in children admitted

Protocol summary

Study aim

Determining the effect of aromatherapy with orange essential oil on pain and nausea-vomiting in children after tonsillectomy in Amir Al-Mo'menin Hospital in Rasht in 2019

Design

This study is a non-blinded clinical trial. The study population will included all patients referred to the diabetes ward of Amir Al-Mo'menin hospital in Rasht. A total of 70 eligible patients will be selected conveniently and randomly assigned to intervention and control groups.

Settings and conduct

This study that will conduct in Amir Al-Mo'menin hospital is non-blinded one. When the child enters the ward of hospital, and before starting the intervention, the amount of pain and severity of nausea and vomiting is measured using a questionnaire and the information is recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children undergoing adenotonsillectomy; Age between 6 to 12 years; No history of respiratory problems; Nausea and vomiting despite receiving antiemetic drugs and 30 minutes after receiving it Exclusion critera:History of allergic rhinitis; Long history of digestive problems; History of respiratory and skin allergies and dermatitis in children and mothers; Chronic pain in children

Intervention groups

In the intervention group, a pad impregnated with two drops of orange essence (Barij essence Company of Kashan) is attached to the collar of a child's clothes with a plastic pin for 6 hours. The distance between the pad and the patient's head should not be more than 20 cm. Each hour, a pad soaked in a new fragrance will be replaced with a pad soaked in an old fragrance.

Main outcome variables

The intensity of pain, Nausea-vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047805N1**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-15, 1399/06/25**
Update count: **0**

Registration date

2020-09-15, 1399/06/25

Registrant information

Name

fatemeh pak nodehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3429 1784

Email address

pak.fateme@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with orange essential oil on pain intensity, nausea and vomiting following adenotonsillectomy in children admitted

Public title
The effect of aromatherapy with orange essential oil on pain intensity, nausea, and vomiting following adenotonsillectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children undergoing adenotonsillectomy Age between 6 to 12 years No history of respiratory problems Nausea and vomiting despite receiving antiemetic drugs and 30 minutes after receiving it
Exclusion criteria:
History of allergic rhinitis The long time history of digestive problems History of respiratory and skin allergies and dermatitis in children and mothers Chronic pain in children
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Using a block randomization method. In this study, the blocks are selected weekly, so that, the intervention group will be evaluated in the first week and in the second week the control group will be evaluated randomly. This method will continue until the required number of sampleswill be obtained. To avoid bias, the start of sampling each week will be subject to the clearance of all survey units in the last week.
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 Islamic Azad University of Khorasgan Branch
Street address
University Blvd, Arghavaniyeh, East Jay St.
City
Esfahan
Province
Isfehan
Postal code
8155139998
Approval date
2020-06-10, 1399/03/21
Ethics committee reference number
IR.IAU.KHUISF.REC.1399.032

Health conditions studied

1

Description of health condition studied
Tonsillectomy
ICD-10 code
J35.1
ICD-10 code description
Hypertrophy of tonsils

Primary outcomes

1

Description
The intensity of pain
Timepoint
30 minutes, 3, 6 and 12 hours after the intervention
Method of measurement
Based on Visual Scale (VAS)

2

Description
Nausea-vomiting
Timepoint
30 minutes, 3, 6 and 12 hours after the intervention
Method of measurement
Based on the Visual Scale (VAS) and Rhodes Nausea-vomiting Intensity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, a pad impregnated with two drops of orange essence (Barij essence Company of Kashan) is attached to the collar of a child's clothes with a plastic pin for 6 hours. The distance between the pad and the patient's head should not be more than 20 cm.Each hour, a pad soaked in a new fragrance will be replaced with a pad soaked in an old fragrance.

Category
Treatment - Other

2

Description
In the intervention group, a pad impregnated with two drops of distilled water is attached to the collar of a child's clothes with a plastic pin for 6 hours. The distance between the pad and the patient's head should not be more than 20 cm. Each hour, a pad soaked in a new fragrance will be replaced with a pad soaked in an old fragrance.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir al-Momenin Hospita

Full name of responsible person
Fatemeh Paak Nodehi

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17 Shahrivar St, Dr. Heshmat Sq, Imam Khomeini St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Mohammad Roholah Yazdani

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m.yazdani@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Fatemeh Paak Nodehi

Position
Master of Nursing Student

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Narges Sadeghi

Position
Faculty member of Islamic Azad University

Latest degree
Ph.D.

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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
Yes - There is a plan to make this available
Title and more details about the data/document
All authors agree.
When the data will become available and for how long
anytime
To whom data/document is available
author
Under which criteria data/document could be used
academic
From where data/document is obtainable
author
What processes are involved for a request to access data/document
Consultation
Comments