

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 include 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 criteria: 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 samples will 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

Isfahan

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 centers1**Recruitment center****Name of recruitment center**

Amir al-Momenin Hospita

Full name of responsible person

Fateme Paak Nodehi

Street address

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

City

Esfahan

Province

Isfahan

Postal code

4153983745

Phone

+98 31 3323 8306

Email

pak.fateme@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr. Mohammad Roholah Yazdani

Street address

University Blvd, Arghavaniyeh, East Jay St.

City

Esfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

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

Fateme Paak Nodehi

Position

Master of Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

University Blvd, Arghavaniyeh, East Jay St.

City

Esfahan

Province

Isfahan

Postal code

8155139998

Phone

+98 31 3535 4001

Email

pak.fateme@gmail.com

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.

Other areas of specialty/work

Nursery

Street address

University Blvd, Arghavaniyeh, East Jay St.

City

Isfahan

Province

Isfahan

Postal code
8155139998
Phone
+98 31 3535 4001
Email
pak.fateme@gmail.com

Person responsible for updating data

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
Street address
University Blvd, Arghavaniyeh, East Jay St.
City
Esfahan
Province
Isfahan
Postal code
8155139998
Phone
+98 31 3535 4001
Email
pak.fateme@gmail.com

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