

# 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 centers****1****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

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**Postal code**

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pak.fateme@gmail.com

**Sponsors / Funding sources****1****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.

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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**

Fateme 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.

**Other areas of specialty/work**

Nursery

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## 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**  
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**Other areas of specialty/work**  
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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