

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of IV Ondansetron on analgesic effects of IV Acetaminophen after pediatric tonsillectomy: a double blinded randomized clinical trial

#### Protocol summary

##### Study aim

The effect of ondansetron on intravenous acetaminophen analgesia after pediatric adenotonsillectomy

##### Design

A randomized controlled clinical trial with parallel groups, three blinded, randomized

##### Settings and conduct

Study Location: Hamedan Besat Hospital Procedure: Blindness in both intervention and control groups will be prescribed intravenous acetaminophen 2 minutes before surgery. These patients will be anesthetized the day before surgery. The surgical technique was the same in all cases. In pain recovery, the patient's pain is measured on a CHEOPS scale. If the pain score is greater than 1 with the CHEOPS criterion, 0.25mg / kg of meperidine will be administered to the patient for analgesia and up to 0.5 mg / kg for analgesia. The time of the first analgesic application and the total dose of adjunctive analgesic will also be recorded. In the event of nausea and vomiting, metoclopramide may be administered as an antiemetic and intravenously.

##### Participants/Inclusion and exclusion criteria

Healthy 1- to 3-year-old children without an underlying disease are candidates for elective adeno-tonsillectomy who will be referred to Hamadan Besat Medical Center during the study period (year 1).

##### Intervention groups

Intravenous ondansetron 0.1 mg / kg in 1 ml volume plus intravenous acetaminophen 1 mg / kg 2 minutes before surgery and acetaminophen suppository every 2 hours to 4 hours

##### Main outcome variables

Reduce the analgesic effect of acetaminophen Increased complications after tonsillectomy

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20160508027793N1**

Registration date: **2019-09-12, 1398/06/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-12, 1398/06/21**

Update count: **0**

#### Registration date

2019-09-12, 1398/06/21

#### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0032

##### Email address

l.halimi@umsha.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-08-15, 1398/05/24

#### Expected recruitment end date

2020-03-14, 1398/12/24

#### Actual recruitment start date

2019-02-20, 1397/12/01

#### Actual recruitment end date

2020-03-14, 1398/12/24

#### Trial completion date

2020-04-08, 1399/01/20

#### Scientific title

The effect of IV Ondansetron on analgesic effects of IV Acetaminophen after pediatric tonsillectomy: a double blinded randomized clinical trial

#### Public title

The IV Ondansetron on analgesic effects of IV Acetaminophen after pediatric tonsillectomy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Inclusion criteria : • Age 4-5 years: Candidate for elective adenotonsillectomy • Parental consent • • No history of psychiatric illness • Do not use the apparatus 2 hours before surgery • Insensitivity to ondansetron or acetaminophen • No history of venous hepatic disease

### Exclusion criteria:

• Failure to cooperate after initial interventions • Failure to show proper pain level • The patient has a decreased level of consciousness.

## Age

From **3 years** old to **12 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: **60**

Actual sample size reached: **53**

## Randomization (investigator's opinion)

Randomized

## Randomization description

For this purpose we will use the Quadratic Block Randomization method. For this purpose, we provide four sheets of paper. On the two sheets the letter I means "Intervention" and on the other two sheets the letter C means "Comparison". Mix the sheets together and place in a drawer. On referral to each eligible patient, one leaflet will be randomly drawn and based on this leaflet, whether I or C, will be assigned to one of the intervention groups receiving ondansetron and acetaminophen or a comparison of acetaminophen recipients. It should be noted that the sheets that have been drawn out will not be returned to the drawer until they have been drawn out. After randomly pulling out all four sheets of all four sheets, all the sheets are returned to the drawer again and the procedure will continue again for the next four patients until the desired sample size is reached.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

In both intervention and control groups, intravenous acetaminophen will be prescribed 2 minutes before surgery, so the patient will not be informed of the prescription drug. Medications are provided by a technician so the anesthesiologist who will measure and record the outcome of the study will not be aware of the type of medication prescribed. In addition, the analyzer will not know the results of the coding of the intervention and comparison groups. Therefore, the study will be conducted in a triple blind manner.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

##### Street address

Opposite of Mardom`s Park , Pazhuhesh crossroad

##### City

Hameedan

##### Province

Hamadan

##### Postal code

6517619664

#### Approval date

2019-08-14, 1398/05/23

#### Ethics committee reference number

IRCT.UMSHA.REC1398.433

## Health conditions studied

### 1

#### Description of health condition studied

Chronic tonsillitis and adenoiditis

#### ICD-10 code

J35.0

#### ICD-10 code description

Chronic tonsillitis and adenoiditis

## Primary outcomes

### 1

#### Description

Painless

#### Timepoint

15 minutes before surgery and every 6 hours to 24 hours

#### Method of measurement

Children's hospital Eastern Ontario Pain Scale (ChEOPS)

## Secondary outcomes

### 1

#### Description

Nausea and vomiting

#### Timepoint

Four times at recovery, 6 hours, 12 hours and 24 hours

after surgery  
**Method of measurement**  
ask

## Intervention groups

### 1

#### Description

Intervention group: Intravenous ondansetron 0.1 mg / kg in 2 ml volume plus intravenous acetaminophen 15 mg / kg 15 minutes before surgery and acetaminophen suppository every 6 hours to 24 hours after surgery

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Intravenous normal saline 2 ml plus acetaminophen 2 mg / kg 15 min before end of surgery and acetaminophen suppository every 6 hours to 24 hours

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Mahshid Nikooseresht

##### Street address

Shahid Beheshti Blv.

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6517619664

##### Phone

+98 81 3262 1515

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besat@umsha.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Saeid Bashiriyan

##### Street address

in front of Mardom's Park, Pazhuhesh Crossroad

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##### Province

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Medical\_faculty@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Hamedan University of Medical Sciences

#### 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Leyla Halimi

##### Position

researcher

##### Latest degree

Master

##### Other areas of specialty/work

Epidemiology

##### Street address

N37 , Ettehad Ally Zolfaghar street , Fatemieh Blv  
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##### Province

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lhhalimi20@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Mahshid Nikooseresht

##### Position

Consultant  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
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in front of Mardom's Park, Pazhuhesh`s crossroad  
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## Person responsible for updating data

**Contact**  
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Hamedan University of Medical Sciences  
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leyla halimi  
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**City**  
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Hamadan

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**Phone**  
+98 81 3822 7471  
**Email**  
lhhalimi20@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Mean pain score

### When the data will become available and for how long

From 2018 to 12019

### To whom data/document is available

Researchers working in academic and scientific institutions

### Under which criteria data/document could be used

statistic analysis

### From where data/document is obtainable

Dr. Mahshid Nikooseresht Niko\_mahshid@yahoo.com

### What processes are involved for a request to access data/document

Send email to assistance professor

### Comments