

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

I.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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashiriyan

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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

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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