Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
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Street address
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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