

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of intravenous Acetaminophen versus intravenous Dexamethasone on post tonsillectomy pain in children between 1 and 12 years old.

Protocol summary

Summary

Actually few studies are available comparing the clinical efficacy of intravenous acetaminophen with other medications such as dexamethasone to decrease postoperative pain and side effects in children. This study has been designed to compare the postoperative side effects in children after tonsillectomy. Participants were randomized to receive either intravenous acetaminophen or dexamethasone. Methods: Eighty four children aged between 1 and 12 years who were candidates for tonsillectomy were randomized using a computer-generated schedule to double-blind treatment with intravenous acetaminophen (15mg/kg) or intravenous dexamethasone (0.1 mg/kg). Children were assessed postoperatively for swallowing pain, pain when opening mouth, ear pain, sore throat, and postoperative nausea and vomiting (PONV) in recovery and on the ward up to 6 hours, as well as at 12 and 24 hours after surgery using visual analogue scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208138075N3**

Registration date: **2012-12-23, 1391/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Minoos Sedaghat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 7141

Email address

m-sedaghat@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-08-31, 1391/06/10

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intravenous Acetaminophen versus intravenous Dexamethasone on post tonsillectomy pain in children between 1 and 12 years old.

Public title

Effects of acetaminophen on post tonsillectomy pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 84 Patients age between 1-12 years, who candidate for tonsillectomy surgery, American Society of Anesthesiologists (ASA) physical status class I & II Exclusion criteria: 1 - Chronic pain or daily intake housing 2- A history of seizures 3 - Liver dysfunction or abnormal liver enzymes 4 - Sensitivity to drugs

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In the recovery room, syringe 10 cc medication was ready by a nurse and were labeled A and B. One of which contains 15 mg of intravenous acetaminophen in one cc and the other, 0.1 mg Dexamethasone in one cc. Intravenous acetaminophen brand apotel UNI PHARMA Manufacturing Plant in Greece and brand Dexamethasone is(Iran) Osvah Decadrol construction. At half an hour to the end of tonsillectomy, based on block randomization table 1 cc of A or B for each kilogram of body weight is injected slowly and only once.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Tehran University of Medical Sciences

Street address

School of Medicine, P.O.BOX: 14155-6447

City

Tehran

Postal code

1417613151

Approval date

2012-12-15, 1391/09/25

Ethics committee reference number

91-03-30-16812-72608

Health conditions studied**1****Description of health condition studied**

Hypertrophy of tonsils

ICD-10 code

J35.0

ICD-10 code description

Chronic diseases of tonsils and adenoids

Primary outcomes**1****Description**

pain

Timepoint

every 12 hours until 24 hours after surgery

Method of measurement

VAS (visual analogous scale)

Secondary outcomes**1****Description**

nausea and vomit

Timepoint

Every12 hours until 24 hours after surgery

Method of measurement

How many time

Intervention groups**1****Description**

In group 1: 15mg/kg iv acetaminophen will be administrated at 30 min before the end of the surgery.

Category

Treatment - Drugs

2**Description**

In group 2: 0.1 mg/kg iv dexamethasone will be administrated at 30 min before the end of the surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

ENT operating theaters of Firoozgar Hospital

Full name of responsible person

Dr Minow Sedaghat

Street address

Niayesh St., Satarkhan Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotohi

Street address

4th Floor, Central Organization of Tehran University of Medical Sciences, Qods Ave., Keshavarz Boulevard

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hazrateh Rasul Akram Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr Minow Sedaghat

Position

MD, Anesthesiologist resident

Other areas of specialty/work

Street address

Niayesh St., Satarkhan Ave.

City

Tehran

Postal code

14455364

Phone

+98 21 6435 2326

Fax

+98 21 6650 9059

Email

m-sedaghat@razi.tums.ac.ir;
sedaghat1357@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hazrateh Rasul Akram Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr Minow Sedaghat

Position

MD, Anesthesiologist resident

Other areas of specialty/work

Street address

Niayesh St., Satarkhan Ave.

City

Tehran

Postal code

14455364

Phone

+98 21 6435 2326

Fax

+98 21 6650 9059

Email

m-sedaghat@razi.tums.ac.ir;
sedaghat1357@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hazrateh Rasul Akram Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr Minow Sedaghat

Position

MD, Anesthesiologist resident

Other areas of specialty/work

Street address

Niayesh St., Satarkhan Ave.

City

Tehran

Postal code

14455364

Phone

+98 21 6435 2326

Fax

+98 21 6650 9059

Email

m-sedaghat@razi.tums.ac.ir;
sedaghat13578@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty