Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous and rectal acetaminophen for postoperative pain control in children following Adenotonsillectomy

Protocol summary

Summary

The aim of this study is to compare analgesic efficacy of intravenous injection of acetaminophen with rectal acetaminophen for postoperative tonsillectomy. In this double-blind randomized clinical trial, 70 patients (3-14 y) with American society of Anesthesiologists (ASA) status I and II will be recruited. Patients with emergency operation, allergy to acetaminophen, concurrent diseases, convulsion, precedence of chronic pain and consumption of analgesics and Acetaminophen in the past two weeks will be excluded from study. The patients are randomized in two groups who receive intravenous Acetaminophen (15mg/kg) or rectal acetaminophen (40mg/kg) after anesthesia induction. The induction and maintenance of anesthesia will be same in both groups. The post-operative pain will be evaluated by Wong-Baker Face Pain Scale (FPS). The homodynamic changes, as well as possible complications will also be determined during first 24 hours hospital stay. The observer and the patients will be blind to the groups. In the recovery room HR,SBP,DBP will be recorded every 15 minutes, pain score (face scale), agitation, Aldret score will be recorded every 15 minutes. When the patients obtain score 8 they will leave recovery room. After operation in the ward, pain score will be measured every 4 hours. In recovery, patients with score of less than 5 will receive IV Fentanyl 0.5 µg/kg and time of receiving analgesic will be recorded. Children will be discharged after 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108194041N5**
Registration date: **2011-09-08, 1390/06/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-09-08, 1390/06/17

Registrant information

Name
Mahin Seyedhejazi
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-10-22, 1390/07/30

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous and rectal acetaminophen for postoperative pain control in children following Adenotonsillectomy

Public title

Comparison of intravenous and rectal acetaminophen for postoperative pain control in children following Adenotonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASAI,II children; 3-14 years old;candidated for adenotonsilectomy in Tabriz Children Hospital. Exclusion criteria: emergency surgery; known allergy to Acetaminophen; history of renal, hepatic, cardiac, respiratory tract diseases; epilepsy; neuromuscular disease; history of chronic pain with analgesic usage & acetaminophen in last 2 week.

Age

From **3 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Golgasht st.

City

Tabriz

Postal code

5136735886

Approval date

2011-04-05, 1390/01/16

Ethics committee reference number

9026

Health conditions studied

1

Description of health condition studied

pain afte adenotonsilectomy

ICD-10 code

J35.3

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

pain after adenotonsilectomy

Timepoint

in recovery every 15 min,in ward every 4 hr

Method of measurement

face pain sceale

Secondary outcomes

1

Description

amount of analgesic usage

Timepoint

every 15 min in recovery ,every 4 hr in ward

Method of measurement

mg/kg

Intervention groups

1

Description

control group: IV acetaminophen 15mg/kg

Category

Treatment - Drugs

2

Description

Interventionl group: rectal acetaminophen 40mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr. Mahin Seyedhejazi

Street address

Tabriz Children Hospital, Sheshkelan st.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person
Dr. Ostad Rahimi

Street address
Golgasht st.

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
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Position
Associate Professor of Anesthesia

Other areas of specialty/work

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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