

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 hemodynamic 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

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 2252

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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: ASA I, 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
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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