

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison the effects of intravenous and rectal acetaminophen on duration of pain control after adenotonsillectomy in children

Protocol summary

Summary

Adenotonsillectomy is the most common surgical procedure in children. One of the most common complications of this surgery is pain that is associated with prolonged recovery, disorders in eating and dehydration. For pain relief various drugs and techniques are used. The aim of this study is the clinical effectiveness comparing between intravenous and rectal acetaminophen. For this reason in a patient – observer blind randomized clinical trial 96 patients from 4 to 10 years old that scheduled for adenotonsillectomy will select (after explaining the process of the trial written informed consent obtained from participants) Then they will divide into two groups randomly, and after induction of general anesthesia the first group rectal will receive acetaminophen 15mg/kg and second group will receive intravenous acetaminophen 10 mg/kg will receive. Agitation and pain (with chipps score) will be recorded and then analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107301138N8**

Registration date: **2011-08-11, 1390/05/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-11, 1390/05/20

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Vice chancellor for Research

Expected recruitment start date

2011-08-01, 1390/05/10

Expected recruitment end date

2011-11-21, 1390/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of intravenous and rectal acetaminophen on duration of pain control after adenotonsillectomy in children

Public title

Comparison the effects of acetaminophen on pain control after adenotonsillectomy in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patirnts candidate for elective adenotonsillectomy surgery (4 – 10 yr); ASA claa I , II
Exclusion criteria:emergency surgery; history of the known sensitivity to acetaminophen; history of liver, renal, respiratory , cardiac diseases, seizure; history of chronic pain with usage of analgesics

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

Ethic committee of Guilan University of Medical Sciences

Street address

Siadati st.

City

Rasht

Postal code

Approval date

2011-05-31, 1390/03/10

Ethics committee reference number

624

Health conditions studied

1

Description of health condition studied

adenotonsillectomy

ICD-10 code

T 17.2

ICD-10 code description

Nasopharynx

Primary outcomes

1

Description

Post operative pain

Timepoint

from beginning of recovery every 15 minutes , in the first

6 hours every 2 hours then up to 24 hours, every 6 hours

Method of measurement

With table

Secondary outcomes

1

Description

Agitation

Timepoint

from beginning of post anesthesia car unit every 15 minutes , in the first 6 hours every 2 hours, then up to 24 hours, every 6 hours

Method of measurement

With scoring table

Intervention groups

1

Description

Group A) Intravenous Acetaminophen (10mg/kg)

Category

Treatment - Drugs

2

Description

Group B) Rectal Acetaminophen (125,250mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Susan Komaii

Street address

First Floor, University Building, Siadati st.

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Sciences, Vice Chancellor for Research

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**

Guilan University of Medical Sciences

Full name of responsible person

Dr Sudabeh Haddadi

Position

Assistant Professor

Other areas of specialty/work**Street address**

Amiralmomenin hospital, 17 Shahrivar st.

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Full name of responsible person

Dr Sudabeh Haddadi

Position

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Web page address**Person responsible for updating data****Contact****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