Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Acetaminophen and Ibuprofen in pain relief and complication management following Adenotonsillectomy in 4-10 year old children.

Protocol summary

Summary

The main objective of this study is to determine the difference between Acetaminophen and Ibuprofen in pain relief following Adenotonsillectomy in children. The study has been designed as a Randomized Clinical Trial which is triple blind with no placebo control group in a single research center.Population which has been chosen as our study instant children are, belong to the range of 4 to 10 years old groups. Inclusion criteria: 1. No Allergy to Non Steroid Anti-Inflammatory Drugs 2. No History of coagulopathy 3. No Renal or Hepatic disorder 4. No Severe Asthma (recently admission or treatment with oral corticosteroid) 5. No Family history of coagulopathy 6. No Evidence of Mental retardation Exclusion criteria: 1. Severe and uncontrollable bleeding during and after surgery 2. Severe pain after surgery which needs additional analgesic Sample size is 50 individuals that are randomly assigned them to two equal groups. Intervention in each group is defined as either administration of Acetaminophen or Ibuprofen . The outcomes of study are: 1. Pain score after surgery (after 6 hours postoperative, after 24 hour, after 48 hour) 2. The number of episodes of nausea and vomiting after surgery (during first day, during first week) 3. Intraoperative bleeding volume 4. Postoperative bleeding (during first day, during first week) 5. Time to start eating of oral liquids, semisolid and solid foods 6. Time to going back to their normal life 7. Overall satisfaction of recovery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071814047N1**
Registration date: **2013-11-07, 1392/08/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-11-07, 1392/08/16

Registrant information

Name

Fatemeh Mirashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

Email address

f-mirashrafi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-12-01, 1392/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Acetaminophen and Ibuprofen in pain relief and complication management following Adenotonsillectomy in 4-10 year old children.

Public title

Comparison of the effect of Acetaminophen and

Ibuprofen in pain relief following Adenotonsillectomy.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- No Allergy to Non Steroid Anti-Inflammatory Drugs 2- No History of coagulopathy 3- No Renal and Hepatic disorder 4- No Severe Asthma (recently admission or treatment with oral corticosteroid) 5- No Family history of coagulopathy 6- No Evidence of Mental retardation Exclusion Criteria: 1- Severe and uncontrollable bleeding during and after surgery 2- Severe pain after surgery which needs additional analgesic

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study has been called triple blind. Treatment allocation is revealed neither to patients nor to the researcher who fills out the questionnaires. In addition the individuals who access the data do not know which treatment is assigned to each patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Sixth floor, central organization of University, next to Ghods Ave, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2012-07-11, 1391/04/21

Ethics committee reference number

673/130/91/د

Health conditions studied

1

Description of health condition studied

Adenotonsillectomy

ICD-10 code

J35.1,J35.

ICD-10 code description

Enlargement of tonsils, Enlargement of adenoids

Primary outcomes

1

Description

Pain score

Timepoint

Six hours postoperative, at the end of first postoperative day, at the end of second postoperative day

Method of measurement

with visual analogue pain scale (1-10 score)

Secondary outcomes

1

Description

Intraoperative bleeding volume

Timepoint

During the surgery

Method of measurement

Amount of bleeding in CC, according to the number of sterile gases that is used during the surgery and amount of blood at suction bottle

2

Description

Bleeding at the first postoperative day

Timepoint

At the end of the first postoperative day

Method of measurement

questionnaire

3

Description

Bleeding during the first postoperative week

Timepoint

At the end of first postoperative week

Method of measurement

questionnaire

4

Description

Nausea

Timepoint

At the end of first postoperative day and at the end of first postoperative week

Method of measurement

questionnaire

5

Description
Vomiting
Timepoint
At the end of first postoperative day and at the end of first postoperative week
Method of measurement
questionnaire

6

Description
Time to start eating of oral liquids
Timepoint
At the end of first postoperative week
Method of measurement
questionnaire

7

Description
Time to start eating of semisolid foods
Timepoint
At the end of first postoperative week
Method of measurement
questionnaire

8

Description
Time to start eating of solid foods
Timepoint
At the end of first postoperative week
Method of measurement
questionnaire

9

Description
Time to going back to their normal life
Timepoint
At the end of first postoperative week
Method of measurement
questionnaire

10

Description
Overall satisfaction of recovery
Timepoint
At the end of first postoperative week
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group 1: Syrup Ibuprofen 10mg/ kg orally, once an hour before surgery and then every 6 hour for 3 days was used. This syrup manufacturing company is Hakim co. in Iran and its concentration is 100 mg per 5 ml.
Category
Treatment - Drugs

2

Description
Intervention group 2: Syrup Acetaminophen 15mg/ kg orally, once an hour before surgery and then every 6 hours for 3 days was used. This syrup manufacturing company is Kimidaru co. in Iran and its concentration is 120 mg per 5 ml.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children’s Medical Center
Full name of responsible person
Fatemeh Mirashrafi
Street address
No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., Keshavarz Blvd.
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
Akbar Fotouhi
Street address
No. 1, Poursina Ave., Qods Ave., Enghelab Ave.
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

ENT research center, Imam Khomeini Hospital

Full name of responsible person

Fatemeh Mirashrafi

Position

Assistant Professor

Other areas of specialty/work

Street address

Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., Keshavarz Blvd., Enghelab St.

City

Tehran

Postal code

Phone

+98 21 6658 1628

Fax

Email

f-mirashrafi@sina.tums.ac.ir

Web page address

http://ikh.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

ENT research center, Imam Khomeini Hospital

Full name of responsible person

Fatemeh Mirashrafi

Position

Assistant Professor

Other areas of specialty/work

Street address

Imam Khomeini Hospital, Dr. Mohammad Gharib Ave., Keshavarz Blvd., Enghelab St.

City

Tehran

Postal code

Phone

+98 21 6658 1628

Fax

Email

f-mirashrafi@sina.tums.ac.ir

Web page address

http://ikh.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Tavakolnejad

Position

Medical student

Other areas of specialty/work

Street address

No. 1, Poursina Ave., Qods St., Enghelab St.

City

Tehran

Postal code

Phone

+98 21 8861 2783

Fax

Email

f.tavakolnejad@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