# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jun 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**
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**Email address**
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**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
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No. 1, Poursina Ave., Qods Ave., Enghelab Ave.
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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

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## Person responsible for updating data

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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*