

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison the effect of pre-operative diclophenac and acetaminophen suppositories on postoperative pain severity in children undergoing tonsillectomy

#### Protocol summary

##### Study aim

This study will be conducted with the aim of comparing the effect of acetaminophen and diclophenac suppositories on pain severity in patients undergoing tonsillectomy.

##### Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 100 patients candidate for tonsillectomy.

##### Settings and conduct

This study will be conducted with the aim of comparing the effect of acetaminophen and diclophenac suppositories on pain severity in 100 patients candidate for tonsillectomy. After inclusion in the study, using block randomization with quadrilateral blocks method the patients will be assigned into two groups; acetaminophen group receiving 10 mg/kg of acetaminophen suppository and diclophenac group receiving 2 mg/kg of diclophenac suppository. These drugs will be given rectally 5 minutes before surgery. Finally, 1, 6, 12 and 24 hours after surgery the pain severity will be measured using visual analogue scale and will be compared together.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All children who are candidate for tonsillectomy; age of 5-15 years old Exclusion criteria: Having syndromic diseases; having underlying diseases

##### Intervention groups

Intervention group 1: will receive 10 mg/kg Acetaminophen suppository 5 minutes before starting surgery Intervention group 2: will receive 2 mg/kg Diclophenac suppository 5 minutes before starting surgery

##### Main outcome variables

Pain severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171110037345N1**

Registration date: **2018-02-21, 1396/12/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-21, 1396/12/02**

Update count: **0**

##### Registration date

2018-02-21, 1396/12/02

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5715

##### Email address

ali.safavi@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-05-22, 1397/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison the effect of pre-operative diclophenac and acetaminophen suppositories on postoperative pain severity in children undergoing tonsillectomy

**Public title**

Comparison the effect of diclophenac and acetaminophen suppositories on pain severity in tonsillectomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All 5-15 years old children who are candidate for tonsillectomy

**Exclusion criteria:**

Having syndromic diseases Having underlying diseases

**Age**

From **5 years** old to **15 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

block randomization with quadrilateral blocks

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan Medical University of Science

**Street address**

Zahedan University of Medical Sciences and Health Services campus, KhaliJe Fars Blv, Doctor Hesabi Sq, Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9916789547

**Approval date**

2017-06-18, 1396/03/28

**Ethics committee reference number**

IR.ZAUMS.REC.1396.16

**Health conditions studied****1****Description of health condition studied**

Hypertrophy of tonsils

**ICD-10 code**

J35.1

**ICD-10 code description**

Hypertrophy of tonsils

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

1, 6, 12 and 24 hours after surgery

**Method of measurement**

Using Visual Analogue Scale (VAS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: 10 mg/kg Acetaminophen suppository 5 minutes before starting surgery

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: 2 mg/kg Diclophenac suppository 5 minutes before starting surgery

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Khatam al Anbiya Hospital

**Full name of responsible person**

Ali Safavi

**Street address**

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

**City**

Zahedan

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Sistan-va-Balouchestan  
**Postal code**  
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**Email**  
ayubabedi48@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Taheri  
**Street address**  
Vice chancellor for research, Zahedan University of  
Medical Sciences, Zahedan  
**City**  
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**Province**  
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9816743463  
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+98 54 3329 5721  
**Email**  
Dr.Taheri@zaums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Zahedan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Ali Safavi  
**Position**  
Medical student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

General Practitioner  
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Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to

make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable