

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Province

Sistan-va-Balouchestan

Postal code

99167889547

Phone

+98 54 3329 5715

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

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+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

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

99167889547

Phone

+98 54 3329 5715

Email

ayubabedi48@gmail.com

Person responsible for scientific 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

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

99167889547

Phone

+98 54 3329 5715

Email

ayubabedi48@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Ali Safavi

Position

Medical student

Latest degree

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Other areas of specialty/work

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Street address

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Email

ayubabedi48@gmail.com

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