

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of analgesic efficacy of celecoxib and acetaminophen in pediatric Tonsillectomy

Protocol summary

Summary

Objective: To investigate the post-operative pain in 200 children after tonsillectomy and to compare the analgesic effect between two drugs: Acetaminophen and Celecoxib. Study design: A randomized double-blind study. Inclusion criteria: 3 - 15 years old children; no growth anomalies; physical or psychological problems; living nearby the hospital; at least one of the parents should have high school education. Exclusion criteria: history of allergy to celecoxib or other NSAIDs; asthma; kidney or liver dysfunction or a hemorrhagic diathesis and sulphonamide allergy; social reasons. Interventions: the first dose of acetaminophen after discharge is consisted of oral suspension 120mg/5 ml, 400 mg at 4 hours after tonsillectomy and then every 6 hours for seven days. The first dose of celecoxib after discharge is consisted of oral suspension 100mg/5 ml, (50mg for children under 25 kg and 100mg for upper) at 4 hours after tonsillectomy and then every 12 hours for seven days. The first and second pain score will be assessed at 4 and 8 hours after operation. The total duration of hospital admission is at least 8 hours. Primary outcome parameter: the intensity of postoperative pain. The questionnaire is going to be used in assessing the post-operative pain, daily activity and also food consumption for 7 days after discharge. To record the intensity of postoperative pain, the simplified version of Visual Analog Scale (VAS) is applied. Parents must express their children's pain on an -point rating scores (0= no pain, 5 = worst pain. Pain will be checked four times a day in two weeks after Tonsillectomy (before breakfast, lunch and dinner and sleeping).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015080919470N29**

Registration date: **2016-12-27, 1395/10/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-27, 1395/10/07

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-09-30, 1394/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic efficacy of celecoxib and acetaminophen in pediatric Tonsillectomy

Public title

Comparison of analgesic efficacy of celecoxib and

acetaminophen in pediatric Tonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 3 - 15 years old children; no growth anomalies; physical or psychological problems; living nearby the hospital; at least one of the parents should have high school education. Exclusion criteria: history of allergy to celecoxib or other NSAIDs; asthma; kidney or liver dysfunction or a hemorrhagic diathesis and sulphonamide allergy; social reasons.

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be performed by referring to the www.randomization.com

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiaz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

lr.sums.rec.1394.s946

Health conditions studied

1

Description of health condition studied

tonsillectomy

ICD-10 code

J35

ICD-10 code description

Chronic disease of tonsils and adenoid

Primary outcomes

1

Description

Pain score intensity

Timepoint

4 times a day; before breakfast, lunch and dinner and sleeping. Two weeks after Tonsillectomy

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Bleeding

Timepoint

Daily

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: The first dose of acetaminophen after discharge will consist of oral suspension 120mg/5 ml, 400 mg at 4 hours after tonsillectomy and then every 6 hours for seven days.

Category

Treatment - Drugs

2

Description

Intervention group 2: The first dose of celecoxib after discharge will consist of oral suspension 100mg/5 ml, (50mg for children under 25 kg and 100mg for upper) at 4 hours after tonsillectomy and then every 12 hours for seven days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Bahar Noori Dolat abadi

Street address

Khalili Hospital, Khalili Street

City

Shiraz

2**Recruitment center****Name of recruitment center**

Dasghib Hospital

Full name of responsible person

Bahar Noori Dolat Abadi

Street address

Dasghib Hospital, Hafezieh Squre, Golestan BLVD.

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research ,Shiraz University of Medical Sciences-7th floor-Central Building of Shiraz University of Medical Sciences , Zand Street

City

Shiraz

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, Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Bahar Nouri Rahmt Abadi

Position

Physician, Anesthesiologist

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

Anesthesiology Department, Shahid Faghihi Hospital, Zand street

City

Shiraz

Postal code**Phone**

+98 71 3647 4270

Fax**Email**

baharnoori64@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University Of Medical Sciences

Full name of responsible person

Mohammad Hosin Eghbal

Position

Anesthesiologist

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

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Postal code**Phone**

+98 71 3647 4270

Fax**Email**

mheghbal@sums.ac.ir

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

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

MS in english teaching, BS in anesthesia, English Consultant

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

5th floor, Mohammad Rasul Allah Research Towe, Khalili Street

City

Shiraz

Postal code**Phone**

+98 71 3647 4270

Fax**Email**

masihifarzaneh@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Statistical Analysis Plan

Data Dictionary

empty