Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 and100mg for upper) at 4 hours after tonsillectomy and then every12 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)

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+98 71 3647 4270

Email address

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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

Ir.sums.rec.1394.s946

Health conditions studied

1

Description of health condition studied

tonsilectomy

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 and100mg for upper) at 4 hours after tonsillectomy and then every12 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
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Dasghib Hospital, Hafezieh Squre, Golestan BLVD.
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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
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Vice Chancellor for Research ,Shiraz University of Medical Sciences-7th floor-Central Building of Shiraz University of Medical Sciences , Zand Street
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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
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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