Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Compare the effect of acetaminophen suppository before and after adenotonsillectomy on reducing pain in children

Protocol summary

Summary

The purpose of this study is to compare the clinical efficacy of acetaminophen suppository inserted before and after adenotonsillectomy on reducing pain.inclusion criterias are: children 7_15 years undergoing adenotonsillectomy؛children with recurrent tonsillitis؛chronic tonsillitis؛obstructive sleep apnea syndrome and exclusion criterias are: known allergy to acetaminophen؛renal or hepatic dysfunction؛use of pain killers during the past 24 hours؛drug abuse؛diarrhea؛dehydration؛bleeding disorders and.for this purpose, in a clinical trial, 100 patients 7 to 15 years undergoing adenotonsillectomy after the description of the clinical trial and obtaining written consent will randomly be assigned to the study and prepare for the first group acetaminophen suppository 5 minutes before the surgery (after intubation) and the second group will receive the same dose of the suppository before extubation after the end of surgery and the need for pain medication and post-operative pain will be evaluated according to the VAS criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083023811N1**
Registration date: **2015-12-07, 1394/09/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-07, 1394/09/16

Registrant information

Name

Atefe Nikjoo

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

nikjoo@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2015-11-06, 1394/08/15

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of acetaminophen suppository before and after adenotonsillectomy on reducing pain in children

Public title

The effect of acetaminophen to reduce pain in tonsillectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: children undergoing adenotonsillectomy؛children 7_15 years with recurrent tonsillitis؛chronic tonsillitis؛obstructive sleep apnea syndrome؛open mouth breathing؛snoring and dysphagia;Exclusion criteria: known allergy to acetaminophen؛renal or hepatic dysfunction؛use of pain

killers during the past 24 hours؛drug abuse (due to the high prevalence in the region)؛ known Favism disease؛diarrhea؛dehydration؛bleeding disorders and act surgery lasted more than 30 minutes.

Age
From **7 years** old to **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
School of Medicine ،College of Medical Sciences and Health Services، Jannat boulevard، Dr Hesabi square، Zahedan

City
Zahedan

Postal code

Approval date
2015-06-28, 1394/04/07

Ethics committee reference number
ir.zaums.rec.1394.147

Health conditions studied

1

Description of health condition studied
Hypertrophy of tonsils and adenoids

ICD-10 code
J35.3

ICD-10 code description
Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description
pain

Timepoint
2 hours, 6 hours, 12 hours and 24 hours after intervention

Method of measurement
visual annalog pain scale

Secondary outcomes

1

Description
The need for pain medication after surgery

Timepoint
Every 1 hour after intervention

Method of measurement
Frequency of consumption

Intervention groups

1

Description
The first group، rectal acetaminophen 40 mg / kg, five minutes before the surgery (after intubation)

Category
Treatment - Drugs

2

Description
The second group،rectal acetaminophen 40mg / kg after the end of surgery and before extubation

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam hospital

Full name of responsible person
Atefe Nikjoo

Street address
Khatam Hospital، Jamejam boulevard، Zahedan

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology

Full name of responsible person

Dr Hooshang Rafighdoost

Street address

Deputy of Research and Technology ،School of Medicine ،College of Medical Sciences and Health Services، Jannat boulevard، Dr Hesabi square، Zahedan

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Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology

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

Zahedan University of Medical Sciences

Full name of responsible person

Dr Gholamali Dashti

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work

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atefeh.nikjoo@yahoo.com

Web page address

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