

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of dextromethorphan and ibuprofen effect on post adenotonsillectomy pain severity

Protocol summary

Study aim

Comparison of dextromethorphan and ibuprofen effect on post adenotonsillectomy pain severity

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 90 patients undergoing adenotonsillectomy

Settings and conduct

This study will be conducted with the aim of comparing the effect of dextromethorphan and ibuprofen effect on post adenotonsillectomy pain severity in 90 patients candidate for adenotonsillectomy. After inclusion in the study, using block randomization method with blocks on 9, the patients will be assigned into three groups; dextromethorphan group receiving 1 mg/kg of dextromethorphan syrup in 10 cc juice, ibuprofen group receiving 10 mg/kg of ibuprofen syrup in 10 cc juice and placebo group receiving 10 cc juice. These drugs will be given orally 30 minutes before surgery. Finally, 1, 2, 4 and 6 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: Age of 3-12 years; Being candidate for adenotonsillectomy Exclusion criteria: Having underlying disease; Having contraindication for using the study drugs

Intervention groups

Intervention group 1: Receiving 1 mg/kg of dextromethorphan syrup in 10 cc juice 30 minutes before the operation Intervention group 2: Receiving 10 mg/kg of ibuprofen syrup in 10 cc juice 30 minutes before the operation Control group: Receiving 10 cc juice 30 minutes before the operation

Main outcome variables

Post-adenotonsillectomy pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180831040914N1**

Registration date: **2018-09-09, 1397/06/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-09, 1397/06/18**

Update count: **0**

Registration date

2018-09-09, 1397/06/18

Registrant information

Name

Javad Keykha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

j.keykha72@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of dextromethorphan and ibuprofen effect on post adenotonsillectomy pain severity		City Zahedan Province Sistan-va-Balouchestan Postal code 9916789547 Approval date 2017-05-07, 1396/02/17 Ethics committee reference number IR.ZAUMS.REC.1396. 17	
Public title Dextromethorphan and ibuprofen effect on post adenotonsillectomy pain Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Age of 3-12 years Being candidate for adenotonsillectomy Exclusion criteria: Having underlying disease Having contraindication for using the study drugs Age From 3 years old to 12 years old Gender Both Phase 2-3 Groups that have been masked - Participant - Care provider		Health conditions studied <u>1</u> Description of health condition studied Adenotonsillectomy ICD-10 code J35 ICD-10 code description Chronic diseases of tonsils and adenoids	
Sample size Target sample size: 90 Randomization (investigator's opinion) Randomized Randomization description Block randomization with blocks of 9 Considering the sample size of 90, 10 blocks with 9 cards (3 cards for each group) will be selected; by selecting each block, 3 patients will be assigned into each group. Blinding (investigator's opinion) Double blinded Blinding description The drugs and placebo will be coded as A, B and C and will be similar in shape so the patient and the caregiver (patient's physician) will be blinded. Placebo Used Assignment Parallel Other design features		Primary outcomes <u>1</u> Description Post-adenotonsillectomy pain severity Timepoint 1, 2, 4 and 6 hours after the operation Method of measurement By using Visual Analog Scale (VAS)	
Secondary Ids empty		Secondary outcomes empty	
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Zahedan University of Medical Sciences Street address Zahedan University of Medical Sciences and Health Services campus, KhaliJe Fars Blv, Doctor Hesabi Sq, Zahedan		Intervention groups <u>1</u> Description Intervention group 1: Receiving 1 mg/kg of dextrometorphan syrup in 10 cc juice 30 minutes before the operation Category Treatment - Drugs <u>2</u> Description Intervention group 2: Receiving 10 mg/kg of ibuprofen syrup in 10 cc juice 30 minutes before the operation Category Treatment - Drugs <u>3</u> Description Control group: Receiving 10 cc juice 30 minutes before the operation Category	

Placebo

Type of organization providing the funding

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al Anbiya Hospital

Full name of responsible person

Javad Keykha

Street address

Khatam al Anbiya Hospital, Jame Jam Blv, Zahedan

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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

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Javad Keykha

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable