Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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; dextrometorphan group receiving 1 mg/kg of dextrometorphan 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 dextrometorphan 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

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

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

Secondary Ids

empty

Ethics committees

1

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
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

Health conditions studied

1

Description of health condition studied
Adenotonsillectomy
ICD-10 code
J35
ICD-10 code description
Chronic diseases of tonsils and adenoids

Primary outcomes

1

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 outcomes

empty

Intervention groups

1

Description
Intervention group 1: Receiving 1 mg/kg of dextrometorphan syrup in 10 cc juice 30 minutes before the operation
Category
Treatment - Drugs

2

Description
Intervention group 2: Receiving 10 mg/kg of ibuprofen syrup in 10 cc juice 30 minutes before the operation
Category
Treatment - Drugs

3

Description
Control group: Receiving 10 cc juice 30 minutes before the operation
Category

Placebo

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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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

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
Javad Keykha

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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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