Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating effects of montelukast added to nasal mometasone in comparison to placebo in the treatment of children with adenoid hypertrophy

Protocol summary

Study aim
This study aims to compare the efficacy of oral montelukast versus placebo in addition to nasal mometason.
Design
Double blinded randomised clinical trial.patients randomly divided into case and control groups
Settings and conduct
Clinic of Bahrami children hospital Double-blinded randomized division of patients into case and control group by odd or even clinic file numbers.
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1)2to14 yrs old 2)Hypertrophied adenoids documented by lateral neck xray and clinically 3) receiving or candidate for receiving nasal mometason 4) absence of contraindications for corticosteroids and monteleukast 5) no history of adenoidectomy 6) patient and/or parents Informed consent Exclusion criteria: 1)history of sensitivity to nasal corticosteroids or antileukotriens 2) craniofacial, neuromuscular or syndromic abnormalities 3)acute upper respiratory tract infection 4)history of oral corticosteroids or antibiotics in the past 2 weeks 5) drug reactions causing medical regimen alterations 6) patients who develop indication for adenoidectomy during trial 7)patient's refusal
Intervention groups
Children aged 2 to 14 years who come to Baharami children hospital clinic who have adenoid hypertrophy with Odd file numbers
Main outcome variables
Nasal speech, sleep snoring, mouth breathing

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180718040520N1**
Registration date: **2020-03-24, 1399/01/05**
Registration timing: **retrospective**

Last update: **2020-03-24, 1399/01/05**
Update count: **0**
Registration date
2020-03-24, 1399/01/05

Registrant information
Name
Bahar Pourroshani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8819 2716
Email address
bahar.pourroshani@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2019-04-21, 1398/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating effects of montelukast added to nasal mometasone in comparison to placebo in the treatment of children with adenoid hypertrophy

Public title
Effectiveness of Monteleukast in treatment of Adenoid Hypertrophy in Children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
hypertrophy of adenoids confirmed clinically and radiologically Current use of nasal Mometason No contraindication for corticosteroids or monteleukast No previous adenoidectomy Patients and parents consent age 2 to 14 years
Exclusion criteria:
Allergic to nasal corticosteroids or antileukotriens Craniofacial, neuromuscular disorders or syndromes Acute upper respiratory tract infection Use of corticosteroids or antibiotics within last 2 weeks drug reactions requiring medication change patients who require surgical treatment while participating patient or parent refusal
Age
From **2 years** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
patients are divided into two groups bye clinic's file numbers. Odd numbers into group A and even numbers into group B.
Blinding (investigator's opinion)
Double blinded
Blinding description
Person who dispenses the drug, data collector and data analyzer and the pateint is not aware of whether a drug or placebo is being given to each patient group. Drug and placebo are given to patients in 30 tablet packages labeled as A and B.Drug and placebo are identical in size, shape, and taste.patient and person delivering the drug are not aware of it being drug or placebo until the end of trial and analysis. Only after the end of the analysis it will be revealed whether group A or group B has received the drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Research Ethics Committee of Tehran School of Medicine
Street address
13th Floor, Block A,
City
Tehran
Province
Tehran
Postal code
1467664969
Approval date
2018-06-30, 1397/04/09
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.196

Health conditions studied

1

Description of health condition studied
Adenoid Hypertrophy
ICD-10 code
J35.2
ICD-10 code description
Hypertrophy of adenoids

Primary outcomes

1

Description
mouth breathing
Timepoint
before intervention and 1 months after and 2 months after intervention
Method of measurement
questionnaire

2

Description
Nasal Voice
Timepoint
before intervention and 1 months after and 2 months after intervention
Method of measurement
questionnaire

3

Description
Snoring

Timepoint
before intervention and 1 months after and 2 months after intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: monteleukast tab daily 5 mg for 2 months plus nasal mometason daily. Patients are followed in clinic or on phone in two sessions.drug is produced in Abidi Pharmaceuticals.
Category
Treatment - Drugs

2

Description
Control group: placebo with same packaging and shape for 2 months plus nasal mometason. Patients are followed in clinic or on phone in two sessions. Placebo is produced in Abidi Pharmaceuticals.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami children hospital
Full name of responsible person
Bahar Pourroshani
Street address
Ansar al-hossein st., Sabalan south st.
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7301 3000
Email
hosp_bahrami@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Shahin Akhondzade
Street address
Keshavarz boulevard
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 6641 8466
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Bahar Pourroshani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Bahrami children hospital, Ansar-ol-hossein st., Sabalan st
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Data will be sent by request online.

When the data will become available and for how long
March 2020 to june2020

To whom data/document is available
Examiners

Under which criteria data/document could be used
By examiners request

From where data/document is obtainable
Main researcher , Bahar Pourroshani, contact by email address bahar.pourroshani@gmail.com

What processes are involved for a request to access data/document
After researcher recieives the email , she will respond the request by email.

Comments