

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 mometasone.

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) 2 to 14 yrs old 2) Hypertrophied adenoids documented by lateral neck xray and clinically 3) receiving or candidate for receiving nasal mometasone 4) absence of contraindications for corticosteroids and montelukast 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 Bahrami 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 by 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 patient 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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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 June 2020

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 receives the email, she will respond
the request by email.

Comments