

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The role of intranasal corticosteroid in treatment of adenoid hypertrophy in children

Protocol summary

Summary

study objective: The role of intranasal corticosteroid treatment on adenoid hypertrophy in children. inclusion criteria: children between 2-14 with hypertrophic adenoid. Exclusion criteria: corticosteroid therapy more than 1 month; children with anatomical defects in head and neck. In this clinical trial (before-after) study, between April 2012 and May 2013, 45 children between 2 to 14 years old who were affected by adenoid hypertrophy and clinical symptoms (snoring, sleep apnea, ...) and had referred to Otorhinolaryngology and Allergy clinics were recruited. The primary outcome was measured with the questionnaires. After doing skin prick test, children were assigned randomly to receive intranasal corticosteroid for 8 weeks. At the end of the 8 week course of treatment, all children were reassessed to evaluate the efficacy of treatment. It is important to mention that the administered medicine was verified with references and is one of the routine treatments in allergic rhinitis, no invasive procedure was done. The process carried out for diagnosis and treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303069429N2**
Registration date: **2013-09-20, 1392/06/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-20, 1392/06/29

Registrant information

Name

Mahnaz Sadeghi shabasteri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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sadeghim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2011-11-05, 1390/08/14

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of intranasal corticosteroid in treatment of adenoid hypertrophy in children

Public title

The role of nasal corticosteroid treatment on Adenoid

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: children between 2-14 with hypertrophic adenoid exclusion: corticosteroid therapy more than 1 month; children with anatomical defects in head and neck

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 45

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Departement of Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Postal code

0098

Approval date

2013-08-22, 1392/05/31

Ethics committee reference number

9280

Health conditions studied

1

Description of health condition studied

هیپرتروفی آدنوئید

ICD-10 code

D10

ICD-10 code description

D10.6

Primary outcomes

1

Description

adenoid size

Timepoint

before and after 8 week of corticosteroid therapy

Method of measurement

clinical symptoms such as snoring ...and adenoid size

Secondary outcomes

1

Description

clinical manifestation and neck radiography

Timepoint

before and 8 weeks after corticostreoidtherapy

Method of measurement

questionnaire

Intervention groups

1

Description

intranasal corticosteroid(Fluticasone),100 milligrams at night is administered for all 45 cases and after 8 week course of treatment, symptoms of adenoid hypertrophy will be evaluated

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy and ENT clinics

Full name of responsible person

ENT specialist

Street address

Children Hospital , Sheshgelan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Students Research Comittee of Tabriz University of Medical Sciences

Street address

Medical Faculty

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

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

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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