Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 hyper trophic 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 shabesteri

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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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:corticostreoid 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 ادنویید
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 clinicas
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

Person responsible for general inquiries

Contact

Name of organization / entity

Medical Faculty

Full name of responsible person

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Position

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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