Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intranasal corticosteroids on nasal airway obstruction, behavioral and neurocognitive dysfunction in children with adenoidal hypertrophy

Protocol summary

Summary

Background: adenoidal hypertrophy is a common condition of childhood, when obstructive sleep apnea occurs adenoidectomy is indicated. In less severe cases, non surgical interventions maybe considered, however few medical alternatives are currently available. Intranasal steroids has used to reduce nasal airway obstruction Objectives:to assess the effectiveness of intranasal corticosteroids for improving nasal airway obstruction in children with adenoid hypertrophy. Materials and methods: 77 children 1-12 years exhibiting adenoid hypertrophy symptom and confirmed with radiologic imaging and without tonsil hypertrophy who were not inclined to surgery were included and divided to two groups. One group was treated with intranasal betamethasone 3 times daily for 3 weeks and the second group was treated with intranasal NaCl solution as placebo. The subjects were assessed for airway obstruction symptoms including, snoring breathing and rhinore, via questionnaire ear examination, first month and third month of treatment. Inclusion criteria: all of the infant 1-12 years with symptomatic adenoid hypertrophy without emergency indication surgery. Exclusion criteria: hypertrophy of adenoid with tonsil hypertrophy and indication emergency surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051813366N1**
Registration date: **2013-06-15, 1392/03/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-15, 1392/03/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2013-07-06, 1392/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intranasal corticosteroids on nasal airway obstruction, behavioral and neurocognitive dysfunction in children with adenoidal hypertrophy

Public title

The effect of intranasal corticosteroids on nasal airway obstruction, behavioral and neurocognitive dysfunction in children with adenoidal hypertrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all of the infant 1-12 years with symptomatic adenoid hypertrophy without emergency indication surgery. Exclusion criteria: hypertrophy of adenoid with tonsil hypertrophy and indication emergency surgery.

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences Ethics Committee

Street address

Near Amiralmomenin hosptial, Sardasht, Arak

City

Arak

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

91-128-2

Health conditions studied

1

Description of health condition studied

Adenoid hypertrophy with snoring and nasal congestion

ICD-10 code

J35

ICD-10 code description

Hypertrophy of adenoids

Primary outcomes

1

Description

snoring

Timepoint

1 , 3 month after treatment

Method of measurement

history and physical examination

2

Description

change of facial bone

Timepoint

1 , 3 month after treatment

Method of measurement

history and physical examination

3

Description

mouth breath

Timepoint

1 , 3 month after treatment

Method of measurement

history and physical examination

4

Description

rhinorea

Timepoint

1 , 3 month after treatment

Method of measurement

history and physical examination

Secondary outcomes

1

Description

Local and systemic compliction of bethamethason

Timepoint

One month after of intervention – 3 month after intervention

Method of measurement

Questionnaire sheet with clinical symptome

Intervention groups

1

Description

in the case group betametason drop TDS two drop used in the nasal cavity and evaluation 1 to 3 Interval according obstractive and infectious symptome

Category

Treatment - Drugs

2

Description
in the control group N/S drop TDS two drop used in the nasal cavity and evaluation 1 to 3 Interval according obstractive and infectious symptome
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Davood Hekmatpo
Street address
Near Amiralmomenin hosptial, Sardasht, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
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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