

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

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Name of organization / entity

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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 Amiralmomentin hospital, 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 complication of bethamethason

Timepoint
One month after of intervention – 3 month after intervention

Method of measurement
Questionnaire sheet with clinical symptom

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 obstructive 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 obstructive 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 hospital, 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

Arak University of Medical Sciences

Full name of responsible person

Dr. Farzad Zamani Barsari

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

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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