Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of Intranasal Corticosteroid (Fluticasone) on Adenotonsillar Hypertrophy

Protocol summary

Study aim
Efficacy of Intranasal Corticosteroid (Fluticasone) on Adenotonsillar Hypertrophy

Design
The study with before & after plan after two weeks of using Nasal Fluticasone

Settings and conduct
Children aged 4 to 10 years with adenotonsillar hypertrophy referred to the clinic of Shohada Gomnam Hospital in Yazd Who have been taking inhaled Fluticasone for two weeks and are being re-examined. How to use the spray was explained in the previous sections.

Participants/Inclusion and exclusion criteria
Children aged 4 to 10 years with adenotonsillar hypertrophy who participate in the study with satisfaction. Symptoms of snoring, rhinorrhea, nasal congestion, and enlarged tonsils in the clinical examination are the conditions for inclusion in the study. Non-entry conditions include anatomical abnormalities, neuromuscular disease, upper respiratory tract infection, allergic rhinitis, recurrent tonsillitis.

Intervention groups
Nasal Fluticasone spray is applied to each nostril every 12 hours for two weeks. No side effects. We do not have a control group.

Main outcome variables
Symptoms of adenotonsillar hypertrophy include rhinorrhea, snoring, nasal congestion, and enlarged tonsils on clinical examination

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210228050524N1**
Registration date: **2021-05-08, 1400/02/18**
Registration timing: **retrospective**
Last update: **2021-05-08, 1400/02/18**
Update count: **0**

Registration date
2021-05-08, 1400/02/18

Registrant information

Name
Hamed Hatefi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3138 0015

Email address
drh_hatefi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-17, 1399/12/27

Expected recruitment end date
2021-04-30, 1400/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Intranasal Corticosteroid (Fluticasone) on Adenotonsillar Hypertrophy

Public title
Efficacy of Intranasal Corticosteroid (Fluticasone) on Adenotonsillar Hypertrophy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 4 to 10 Years Old With Adenotonsillar Hypertrophy Existence Of Snoring Existence Of Enlarged tonsils in clinical examination Existence Of Nasal congestion Existence Of Rhinorrhea

Exclusion criteria:

Existence Of Anatomical Abnormalities Existence Of Neuromuscular Disease Existence Of Upper Respiratory Tract Infections Existence Of Allergic Rhinitis Existence Of Recurrent Tonsillitis

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The ENT specialist will give the medicine to the patient for two weeks after the evaluation. The evaluator is not aware of the symptoms before or after treatment. And examines the evaluated questionnaire to understand the result

Placebo

Not used

Assignment

Single

Other design features

A group with a before & after plan . The drug is routine and has been used before and has no side effects

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Medical Sciences

Street address

Ali Ibn Abitaleb Medical School, Islamic Azad University Of yazd, Shohada Gomnam Boulevard, Safaeieh, Yazd

City

Yazd

Province

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Postal code

8916877318

Approval date

2021-03-08, 1399/12/18

Ethics committee reference number

IR.IAU.Yazd.REC.1399.066

Health conditions studied

1

Description of health condition studied

Efficacy of Intranasal Corticosteroid (Fluticasone) on Adenotonsillar Hypertrophy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Adenotonsillar Hypertrophy in clinical examination and symptoms of nasal congestion, snoring, rhinorrhea

Timepoint

Two Weeks

Method of measurement

Clinically and according to the opinion of the ENT Specialist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, patients aged 4 to 10 years with the described symptoms are analyzed. They take Fluticasone nasal spray for two weeks. We do not have a control group .According to an ENT specialist, patients under the age of 12 should use puff every 12 hours on each side of the nose. Each puff contains 50 micrograms. The price of both Iranian and foreign types was the same. We did not require the patient to use the Iranian or foreign type or the specific type of company. Iranian type that was mostly available in the market was from Sina Daroo Company and 20 ml in a plastic spray pump. The drug is a white suspension. It should be shaken before consumption. Insert the spray head into one of the nostrils and manually block the other nostril. While breathing through the nose and with the mouth closed, push the spray all the way in while inhaling. If they miss a dose, they can take it immediately, but if it is time for the next dose, there is no need to take a missed dose or double the next dose .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic Of Shohada Kargar Hospital In Yazd

Full name of responsible person
Dr Hamed Hatefi. ENT Specialist

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Shohada Kargar Hospital, Modarres Boulevard, Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Dr Hamed Hatefi

Position
ENT Subspecialty

Latest degree
Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat

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Yazd: Shahid Pakenjad Boulevard, after Moallem Square, next to Bahareh Hotel, at the beginning of Javad Al-Aimeh Alley

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available