Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect and Comparison Between Combine Therapy by Mometasone Furoate and Azelastine with Single Therapy by Mometazone Furoate or Azelastine on Adenoid Size and Obstructive Symptoms in Patients Referring to ENT Clinic

Protocol summary

Study aim
Effect and Comparison Between Combine Therapy by Mometasone Furoate and Azelastine with Single Therapy by Mometazone Furoate or Azelastine on Adenoid Size and Obstructive Symptoms

Design
The first group receives spray Mometasone, the second group receives Azelastine and the third group receives Mometasone and Azelastine; 1 puff in each nostril twice a day during 30 days. A randomized double-blind clinical trial is conducted on 120 patients undergoing surgery with spinal anesthesia.

Settings and conduct
Patients are referred to ENT clinic of al-Zahra hospital. The patients are randomly divided into three groups including those who receive Mometasone (a), Azelastine (b) and Mometasone and Azelastine (c). The Participants, Care provider, Outcome assessor, and Data analyser are not aware of the drug type and the investigator deciphers the codes after data analysis.

Participants/Inclusion and exclusion criteria
Included criteria: 6 to 12 years old; Children With Hypertrophy of Adenoid Grade 3 and 4 According to Cassano Grading Excluded criteria: History of Adenoidectomy

Intervention groups
They are divided into three groups A, B, and C. The first group Mometasone, the second group received Azelastine and third group received Mometasone and Azelastine

Main outcome variables
Obstruction stmptoms and size of Adenoid

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200612047740N1**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **prospective**

Last update: **2020-06-23, 1399/04/03**
Update count: **0**

Registration date
2020-06-23, 1399/04/03

Registrant information

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Hossein Naderi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-05, 1399/04/15

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect and Comparison Between Combine Therapy by Mometasone Furoate and Azelastine with Single Therapy by Mometazone Furoate or Azelastine on Adenoid Size and Obstructive Symptoms in Patients Referring to ENT Clinic

Public title
Effect of Combine Therapy by Mometasone Furoate and Azelastine with Single Therapy by Mometazone Furoate or Azelastine on Adenoid Size and Obstructive Symptoms in Patients Referring to ENT Clinic
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
6 to 12 Years old Children With Hypertrophy of Adenoid Grade 3 and 4 According to Cassano Grading
Exclusion criteria:
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are Randomly Assigned to the Groups of A, B and C Using Randomization Software
Blinding (investigator's opinion)
Double blinded
Blinding description
Nurse Participating in this Study, Give each Patient Code A, B and C According to Patients Number and classification. Doctor Checking Complications is not Aware of Using Drugs. Also Information Inserts to SPSS in the Form of Code and analyzer is Blind to the Classifications. All Drugs are Prepared and Placed at the Same Volume and Homogeneously by Investigator
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-03-13, 1398/12/23
Ethics committee reference number
IR.MUI.MED.REC.1398.713

Health conditions studied

1

Description of health condition studied
Obstruction Symptoms and Size of Adenoid
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Obstructive Sleep Apnea
Timepoint
At the Beginning and End of 30 Days Treatment Duration
Method of measurement
Berlucchi Grading

2

Description
Night Snoring
Timepoint
At the Beginning and End of 30 Days Treatment Duration
Method of measurement
Berlucchi Grading

3

Description
Cough
Timepoint
At the Beginning and End of 30 Days Treatment Duration
Method of measurement
Berlucchi Grading

4

Description
Rhinorrhea
Timepoint
At the Beginning and End of 30 Days Treatment Duration
Method of measurement
Berlucchi Grading

5

Description

Nasal obstruction

Timepoint

At the Beginning and End of 30 Days Treatment Duration

Method of measurement

Berlucchi Grading

6

Description

Adenoid size/nasopharyngeal depth ratio

Timepoint

At the Beginning and End of 30 Days Treatment Duration

Method of measurement

Lateral Nasopharynx Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Initially, personal consent is obtained from the patients. Then nasal spray of Mometasone is used in each nostril, 1 puff, twice a day (50 micro gram in each puff) overally 200 micro gram a day for 30 days and obstructive symptoms is evaluated in the beginning and end of the treatment period

Category

Treatment - Drugs

2

Description

Intervention group B: Initially, personal consent is obtained from the patients. Then nasal spray of Azelastine is used in each nostril, 1 puff, twice a day (125 micro gram in each puff) overally 500 micro gram a day for 30 days and obstructive symptoms is evaluated in the beginning and end of the treatment period

Category

Treatment - Drugs

3

Description

Intervention group C : Initially, personal consent is obtained from the patients. Then nasal spray of Azelastine and Mometasone is used in each nostril, 1 puff, twice a day for 30 days and obstructive symptoms is evaluated in the beginning and end of the treatment period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra hospital

Full name of responsible person

Hossein Ghazavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Jamileh Haghirzavare
Position
Medical student/ Intern
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Title and more details about the data/document
Only registered symptoms can be published without mentioning the names of the participants
When the data will become available and for how long
Starting the access period 6 months after printing results
To whom data/document is available
Only available to scholars working in academia and academia
Under which criteria data/document could be used
Written request via email and university approval
From where data/document is obtainable
By contacting the corresponding author
What processes are involved for a request to access data/document
After the email is received by the applicant, it takes one week to agree The university will be obtained and then will be notified to the requestor. Maximum of this process takes ten days.
Comments