

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 symptoms 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

##### Name

Hossein Naderi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3568 5233

##### Email address

hossein.naderi1374@gmail.com

##### 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

Isfahan

##### 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  
**Street address**  
Soffeh boulevard, Shahid Kesari highway  
**City**  
Isfahan  
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hossein.naderi1374@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Shaghyegh Haghjoo  
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research@mui.ac.ir

**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 Haghizavare

**Position**

Medical student/ Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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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**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hossein Ghazavi

**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**