

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 2026

### Therapeutic effects of fluticasone nasal spray on clinical symptoms and serum IgE of patients with allergic sinonasal polyposis: A clinical trial

#### Protocol summary

##### Study aim

To assess the effects of fluticasone nasal spray on symptoms and serum IgE of patients with allergic sinonasal polyposis

##### Design

This is a non-blinded, single-group clinical trial. The trial is performed on 34 eligible patients with allergic sinonasal polyposis referring to Ghaem Hospital and Imam Reza Hospital in Mashhad from December 2016 to March 2018. Before intervention, clinical symptoms are recorded, Sino-nasal Outcome Test-22 (SNOT22) is completed, and serum IgE is measured. Then, fluticasone nasal spray with the Flomist brand is prescribed for patients for 4 weeks. At the end of the intervention, the patients will be evaluated in terms of serum IgE levels and clinical symptoms, and SNOT22 will be completed again.

##### Settings and conduct

The trial is performed in the ENT Clinic of Ghaem Hospital and Imam Reza Hospital of Mashhad. The physician responsible for assessing the clinical symptoms and completing SNOT22 as well as the expert in laboratory tests were blind to the study.

##### Participants/Inclusion and exclusion criteria

Main inclusion criteria comprise of grade 2 nasal polyposis or lower grades and positive skin prick test. Main exclusion criteria involve pregnancy and application of nasal or systemic corticosteroid during the past month.

##### Intervention groups

This is a single-group study. Every 12 hours, the patients receive 2 puffs of fluticasone nasal spray (Flomist brand) in each nostril for 4 weeks.

##### Main outcome variables

Serum IgE level and Sino-nasal Outcome Test-22 results

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140519017756N40**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

##### Registration date

2018-03-14, 1396/12/23

##### Registrant information

###### Name

Mohammad Bagher Roozgar

###### Name of organization / entity

Birjand University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3239 5680

###### Email address

mbroozgar@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic effects of fluticasone nasal spray on clinical symptoms and serum IgE of patients with allergic

sinonasal polyposis: A clinical trial

**Public title**  
Effects of fluticasone nasal spray on clinical symptoms and serum IgE

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
grade 2 nasal polyposis or lower grades positive skin prick test signed informed consent age more than 18 years old  
**Exclusion criteria:**  
pregnancy use of nasal or systemic corticosteroid during the past month

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **34**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
The physician responsible for assessing the clinical symptoms and completing SNOT22 as well as the expert in laboratory tests were blind to the study.

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Daneshgah Ave.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138735499

#### Approval date

2016-08-03, 1395/05/13

#### Ethics committee reference number

IR.MUMS.fm.REC.1395.202

## Health conditions studied

### 1

#### Description of health condition studied

allergic sinonasal polyposis

#### ICD-10 code

J.33

#### ICD-10 code description

Nasal polyp

## Primary outcomes

### 1

#### Description

IgE serum level

#### Timepoint

Before and after intervention

#### Method of measurement

laboratory kit to measure IgE serum level

### 2

#### Description

Sino-nasal Outcome Test-22 score

#### Timepoint

Before and after intervention

#### Method of measurement

Sino-nasal Outcome Test-22

## Secondary outcomes

### 1

#### Description

Change in Polyps Grade

#### Timepoint

Before and after intervention

#### Method of measurement

Rhinoscopy and nasal endoscopy

## Intervention groups

### 1

#### Description

Intervention group: Every 12 hours, the patients receive 2 puffs of fluticasone nasal spray (Flomist brand) in each nostril for 4 weeks.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

ENT Clinic of Ghaem Hospital

**Full name of responsible person**

Dr Mehdi Bakhshayi

**Street address**

Ahmadabad Ave.

**City**

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**Province**

Razavi Khorasan

**Postal code**

9138735499

**Phone**

+98 51 3840 0000

**Email**

bakhshaeem@mums.ac.ir

## 2

### Recruitment center

**Name of recruitment center**

ENT Clinic of Imam Reza Hospital

**Full name of responsible person**

Dr Shahriar Mohammadreza Sharifian

**Street address**

Daneshgah Ave.

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Razavi Khorasan

**Postal code**

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**Phone**

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**Email**

SharifianSh@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Daneshgah Ave.

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**Phone**

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tafaghodim@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohammadsadegh Alimardani

**Position**

ENT specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

Imam Reza Hospital, Daneshgah Ave.

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

bakhshaeem@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Shahriar Mohammadreza Sharifian

**Position**

ENT specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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SharifianSh@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
Mohammad Bagher Roozgar  
**Position**  
Translator  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Others  
**Street address**  
Ghaffari Ave.  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9717853577  
**Phone**  
+98 56 3239 5680  
**Email**  
roozgar@BUMS.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

Deidentified Individual Participant Data Set will be provided in an excel file and provided on the research project website: <http://yon.ir/PkRy6>

### When the data will become available and for how long

when the study is completed and for 5 years

### To whom data/document is available

Those who refer to the project's website

### Under which criteria data/document could be used

Only for research purposes

### From where data/document is obtainable

the research website addressed at  
<http://yon.ir/yon.ir/PkRy6>

### What processes are involved for a request to access data/document

If a request is delivered via email, the deidentified data file will be sent within 10 days.

### Comments