

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of beclomethasone aqueous spray and aerosol delivery system in nasal polyps: A randomized control trial

Protocol summary

Study aim

Determination and comparison of the efficacy of aqueous and aerosol beclomethasone sprays in patients with nasal inflammatory polyps

Design

A three phase clinical trial with two intervention groups, in parallel, double-blind, randomized with simple method, with sample size of 70

Settings and conduct

The present study is a double-blind randomized clinical trial. The target population are the patients referring to Alzahra and Kashani Hospital's clinic with a diagnosis of nasal polyposis during the year 1397-98. Patients are randomly divided into two groups. Patients in the first group are treated with beclomethasone nasal spray 50 µg/dose 2 puff in each nose per day and the second group with oral aerosol spray 50 µg/dose 2 puff in each nose per day. Duration of treatment is 2 months. For the purpose of blinding neither patients nor researcher are aware of the type of treatment each group receives.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients from the age of 18-55 years who suffer from inflammatory nasal polyps. Obtaining written consent to participate in the study Exclusion criteria: Previous sensitivity to beclomethasone, Pregnancy or breast-feeding, Severe kidney, heart, liver, neurologic, collagen-vascular, malignancy disease, untreated bacterial or fungal infection, History of trauma and facial fractures. Use of systemic or topical steroids 30 days before study, nasal decongestant, antihistamines, sodium cromolyn, anticholinergics for 7 previous days, use of cardiovascular drugs, neuroleptics, hormones or any drug that causes allergic rhinitis. Tobacco consumption

Intervention groups

Patients in the first group are treated with beclomethasone nasal spray 50 µg/dose 2 puff in each nose per day and the second group with oral aerosol spray 50 µg/dose 2 puff in each nose per day.

Main outcome variables

The sino-nasal outcomes test-22 score, Lund-Mackay score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N32**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-22, 1398/12/03

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A copmarison of beclomethasone aqueous spray and aerosol delivery system in nasal polyps: A randomized control trial

Public title

Comparison of aqueous and aerosol beclomethasone sprays in nasal polyps

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients from the age of 18-55 years who suffer from inflammatory nasal polyps Obtaining written consent to participate in the study

Exclusion criteria:

Previous sensitivity to beclomethasone Pregnancy or breast-feeding Severe kidney, heart, liver, neurologic, collagen-vascular, malignancy disease, untreated bacterial or fungal infection History of trauma and facial fractures Use of systemic or topical steroids 30 days before study, nasal decongestant, antihistamines, sodium cromolyn, anticholinergics for 7 previous days, use of cardiovascular drugs, neuroleptics, hormones or any drug that causes allergic rhinitis Tobacco consumption

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample was randomly divided into two groups of 35 patients. Each envelope containing one of the two labels A and B represented one of the intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of blinding, neither the patients nor the researchers were aware of the type of treatment each group received until the completion of the study. The treatments were divided into two groups as closed packages with codes A and B that were assigned to group A packages containing code A and group B packages containing code B.

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

Isfahn University of Medical Sciences, Hezar Jarib St, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2019-05-18, 1398/02/28

Ethics committee reference number

IR.MUI.MED.REC.1398.503

Health conditions studied**1****Description of health condition studied**

Inflammatory nasal polyp

ICD-10 code

J33.9

ICD-10 code description

Nasal polyp, unspecified

Primary outcomes**1****Description**

The sino-nasal outcomes test-22 average score

Timepoint

Before intervention and 2 months after intervention

Method of measurement

The sino-nasal outcomes test-22 questionnaire

2**Description**

Lund-Mackay average score

Timepoint

2 months after intervention (one time)

Method of measurement

Sinus CT scan

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Patients in the first group are treated with beclomethasone nasal spray produced by Raha pharmaceutical company 50 µg/dose 2 puff in each nose per day for 2 months.

Category

Treatment - Drugs

2

Description

Second intervention group: Patients in the second group are treated with beclomethasone oral aerosol spray produced by Raha pharmaceutical company 50 µg/dose 2 puff in each nose per day for 2 months. For the use of beclomethasone oral spray, the nasal spray attachment is placed on the oral spray.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Ahmad Rezaeian

Street address

Soffeh Boulevard

City

Isfahan

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Isfahan

Postal code

7346181746

Phone

+98 31 3445 2031

Email

ahmadrezaeian@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Isfahan University of Medical Sciences, Hezar Jarib Avne

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Phone

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Farajzadegan@med.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

Ahmad Rezaeian

Position

Professor of ear, nose and throat

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Alzahra hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Rezaeian

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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