Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A copmarison 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 Ansaripour

Name of organization / entity
Shahrekord University of Medical Sciences

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Iran (Islamic Republic of)

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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
Isfehan
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
Province
Isfehan
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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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
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Person responsible for scientific inquiries

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Full name of responsible person

Ahmad Rezaeian

Position
Professor of ear, nose and throat

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Person responsible for updating data

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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