Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of Azelastine spary with budesonide spary in patient with allergic rhinits that admitted to khatam alanbia hospital in Zahedan in2017

Protocol summary

Study aim

Determination of the effect of Azelastine spary with budesonide spary in patient with allergic rhinits that admitted to khatam alanbia hospital in Zahedan in2017

Design

in this study 80 patients ranges 5-18, 18-40 and more than 40 years will be divided in two groups randomly and be treated with budesonide and azalestin spray. groups are matched for age and sex,

Settings and conduct

This study was performed as a clinical trial in the ENT department of Khatam-ol-Anbia Hospital in Zahedan. The study population included all referral patients who were treated by an ENT specialist during the year 96, according to history and clinical findings with the diagnosis of allergic rhinitis. Patients who are referred to the ENT department for allergic rhinitis and treated Patients divided to the two treatment groups are assigned to the first group with azelaestin spray and the second group is given with budesonide spray. Patients will evaluated for five signs.

Participants/Inclusion and exclusion criteria

Major inclusion is patients with allergic rhinitis and exclusions are pregnancy, infection, asthma and adenoid hypertrophy.

Intervention groups

Intervention group includes volunteers who received azalestin spray(allergodil 0.1% 125microgram), Intervention group includes volunteers who received budesonide spray(FRENOLYN inhaler 200micorgram/dose 200 dose) and control group includes volunteers who received placebo

Main outcome variables

treatment status of allergic rhinitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035536N2**
Registration date: **2018-04-18, 1397/01/29**
Registration timing: **retrospective**

Last update: **2018-04-18, 1397/01/29**
Update count: **0**

Registration date

2018-04-18, 1397/01/29

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4245 0395

Email address

mansour.sh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison the effect of Azelastine spary with budesonide spary in patient with allergic rhinits that admitted to khatam alanbia hospital in Zahedan in2017

Public title
omparison the effect of Azelastine spary with budesonide spary in patient with allergic rhinits

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
the absence of patients with non-allergic rhinitis pregnant women those with acute or chronic upper respiratory infections asthmatic patients adenoid hypertrophia

Exclusion criteria:
those who have been ill during the study for any reason Did not complete the administration of the prescriptive or incomplete treatment cases of seasonal allergic rhinitis patients exposed to inhaled chemicals

Age
From **5 years** old to **90 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is such that after the arrival of patients, patients are classified into triple blocks and fall into one of two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethis committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2017-10-29, 1396/08/07

Ethics committee reference number
ir.zaums.rec.1396.230

Health conditions studied

1

Description of health condition studied
Allergic rhinitis

ICD-10 code
j30.2

ICD-10 code description
Other seasonal allergic rhinitis

Primary outcomes

1

Description
Recovery situation

Timepoint
30 days after the first visit

Method of measurement
The symptoms of the disease that the patient is referring to include nasal congestion, itching of the eyes, and lips.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group includes volunteers who received azalestin spray

Category
Treatment - Drugs

2

Description
Intervention group: volunteers who received budesonide spray

Category
Treatment - Drugs

3

Description
Control group: control group includes volunteers who received placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam-Ol-Anbia Hospital

Full name of responsible person
Dr Reza Ghariby

Street address
Khatam-Ol-Anbia Hospital, Jam e Jam Avenue, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 0501

Email
khatamhospital_zah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Dr Hushang Rafighdust

Street address
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Phone
+98 54 3329 5715

Email
public@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Dr Reza Ghariby

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 0501

Email
khatamhospital_zah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Dr Reza Ghariby

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9815733169

Phone
+98 54 3322 0501

Email
khatamhospital_zah@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Dr Reza Ghariby

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743175

Phone
+98 54 3329 5718

Email
khatamhospital_zah@yahoo.com

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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
proposal

When the data will become available and for how long
2018

To whom data/document is available
Public population

Under which criteria data/document could be used
In order to do research

From where data/document is obtainable
Zahedan University of Medical Sciences website

What processes are involved for a request to access data/document
Depending on the site, you can see the documentation.

Comments