

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Evaluating the Effects of Intranasal Injection of Botulinum Toxin-A Compared with Cetirizine on Symptoms of Rhinitis in Adult Patients with Allergic Rhinitis

Protocol summary

Summary

The aim of this study was to evaluate the effects of intranasal Botulinum Toxin-A injection and compare it with cetirizine on symptoms of allergic rhinitis. Fifty adult patients with allergic rhinitis, according to the Allergic Rhinitis and its Impact on Asthma criteria (ARIA), were included into the study, consecutively. Patients randomly received a single dose of intranasal injection of BTX-A (75 IU) or cetirizine (10 mg/day for two months). As the primary outcome, symptoms of rhinitis (based on ARIA) were assessed every two weeks for two months. Quality of life, as the secondary outcome, was evaluated before and after the study using the Rhinasthma questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208261579N3**

Registration date: **2012-10-03, 1391/07/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-10-03, 1391/07/12

Registrant information

Name

Ali Gholamrezaei

Name of organization / entity

Medical Students' Research Center, Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-12-23, 1389/10/02

Expected recruitment end date

2011-12-23, 1390/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effects of Intranasal Injection of Botulinum Toxin-A Compared with Cetirizine on Symptoms of Rhinitis in Adult Patients with Allergic Rhinitis

Public title

Botulinum Toxin-A Compared with Cetirizine in the Treatment of Allergic Rhinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Adult patients with allergic rhinitis according to the Allergic Rhinitis and its Impact on Asthma criteria, 2- Having at least three symptoms of sneezing, nasal congestion, and rhinorrhea. Exclusion criteria: 1- History of nasal anatomic abnormality, 2- Persistent asthma, 3- Long term use of systemic corticosteroids, 4- Malignancy, tuberculosis, diabetes mellitus, or other chronic systemic disease, 5- History of rhinoplasty, 6- Pregnant women, 7- Being on local

corticosteroids at the time of enrollment.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients were randomized to the groups based on random table numbers generated by random allocation software

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street, Vice Chancellor for Research, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2010-12-23, 1389/10/02

Ethics committee reference number

388160

Health conditions studied

1

Description of health condition studied

Allergic rhinitis

ICD-10 code

J30

ICD-10 code description

Vasomotor and allergic rhinitis

Primary outcomes

1

Description

Sneezing

Timepoint

Baseline and every two weeks for two months

Method of measurement

Allergic Rhinitis and its Impact on Asthma Questionnaire

2

Description

Rhinorrhea

Timepoint

Baseline and every two weeks for two months

Method of measurement

Allergic Rhinitis and its Impact on Asthma Questionnaire

3

Description

Nasal congestion

Timepoint

Baseline and every two weeks for two months

Method of measurement

Allergic Rhinitis and its Impact on Asthma Questionnaire

4

Description

Nasal itching

Timepoint

Baseline and every two weeks for two months

Method of measurement

Allergic Rhinitis and its Impact on Asthma Questionnaire

5

Description

Eye irritation

Timepoint

Baseline and every two weeks for two months

Method of measurement

Allergic Rhinitis and its Impact on Asthma Questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and two months after the study

Method of measurement

Rhinasthma Questionnaire

2

Description

Nasal dryness

Timepoint

Every two weeks for two months

Method of measurement

Interview with patient

3

Description

Epistaxis

Timepoint

Every two weeks for two months

Method of measurement

Interview with patient

4

Description

Sleepiness

Timepoint

Every two weeks for two months

Method of measurement

Interview with patient

5

Description

Blurred vision

Timepoint

Every two weeks for two months

Method of measurement

Interview with patient

Intervention groups

1

Description

Intervention: Patients in the intervention group were treated with a single dose intranasal injection of BTX-A (Dysport, Ipsen Biopharm, Wrexham, UK). The procedure was applied while the patients were in sitting position. Local intranasal anesthesia was done with 10% lidocaine sprayed 10 minutes before the injection. Each vial of 495 IU BTX-A was diluted with 3.3 cc of distilled water (150 IU/cc), and 0.5 cc (75 IU each nasal cavity) of this solution was slowly injected with insulin needle into the anterior part of each inferior turbinate.

Category

Treatment - Drugs

2

Description

Control: Patients in the control group were treated with cetirizine (Abidi Co., Tehran, IRAN) 10 mg once daily for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr. Saghi Amini

Street address

Department of Otorhinolaryngology Head and Neck surgery, Alzahra Hospital, Soffeh Ave.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Saghi Amini

Position

MD, Otorhinolaryngologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty