# 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
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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**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*