

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effects of Botulinium Toxin -A in perennial allergic rhinitis patients resistant to conventional treatments

Protocol summary

Summary

The main goal of this study was to examine the effects of Botulinium Toxin-A in relieving symptoms of patients with perennial allergic rhinitis, who have been treated with antihistamines and corticosteroids for the past three years, but no recovery obtained. 40 male and female patients, between ages 20-40 years from clinics of (Pasargad; Karimkhan; Saeed and the University of Social Welfare and Rehabilitation Sciences), based on inclusion (chronic allergic rhinitis for the past three years ;Have not been cured with above mentioned medications) and exclusion criteria (chronic sinusitis; asthma and or having other diseases), were selected. Prior to interventions, research goals discussed, informed consents obtained voluntarily and then patients got divided randomly into two intervention (n=20) and control (n=20) groups. The intervention group received 100 IU of Botulinium Toxin-A, mixed with nasal tampons(10 cm) and control group with the same method, but tampons mixed with Normal Saline which remained in their intranasal cavities for 30 minutes. Both groups were not aware of their type of treatments. Symptoms assessed via a pre-designed, closed-questionnaire charts for itching (eyes, ears and nose); sneeze and rhinorrhea, which all graded from intervals of no symptoms (0) to sever (10). Scores collected in both groups for analysis in pre and post- intervention periods of (1, 3, 6 and 12 weeks) for analysis.

General information

Acronym

BTX-A=Botulinium Toxin type A

IRCT registration information

IRCT registration number: **IRCT201206079963N1**

Registration date: **2012-08-03, 1391/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-03, 1391/05/13

Registrant information

Name

Hashem Shemshadi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-05-01, 1391/02/12

Expected recruitment end date

2012-08-02, 1391/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Botulinium Toxin -A in perennial allergic rhinitis patients resistant to conventional treatments

Public title

Effects of Botulinium Toxin-A in perennial allergic rhinitis patients resistant to conventional treatments

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Males and females age between 20-40; Having perennial (minimum of three years) allergic rhinitis who have received conventional treatments with no results; Having a minimum educational level (high school diploma); Being stable in emotional,physical and other health status suitable for entering study ; Informed consent to be understood and be signed voluntarily. Exclusion criteria: Ages below 20 or above 40 years; History of chronic sinusitis,asthma and or other systemic disoredrs ; History of using Botulinium Toxin type -A for any reason; Rejecting to accept and or signing the informed consent.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University Ethics Committee

Street address

Evin-Daneshjoo Blvd.-Koodakyar St.

City

Tehran

Postal code

1985713834

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

91/801/1/6020

Health conditions studied

1

Description of health condition studied

perennial allergic rhinitis

ICD-10 code

J30.3

ICD-10 code description

other allergic rhinitis/perennial allergic rhinitis

Primary outcomes

1

Description

relieving symptoms of perennial allergic rhinitis such as itching(eyes,ears and nose),sneez and rhinorrhea after intervention

Timepoint

1,3,6 and 12 weeks post intervention

Method of measurement

symptoms chart converting qualitative symptoms of itching(eyes,ears,nose),sneez and rhinorrhea to quantitative from no symptoms(0) to worst symptoms(10) .Scorings are collected in both groups for final statistical analysis.

Secondary outcomes

1

Description

Observing any drug`s side effects in intervencion group.

Timepoint

1,3,6 and 12 weeks post intervention

Method of measurement

Recording any kinds of side effects in pre-designed chart related to each patient from degrees of not having (0) to sever degrees of side effects (10)

Intervention groups

1

Description

Intervention group; Treated with 100 IU Botulinium Toxin type A admixed with 10cm nasal tampons which remained in their nasal cavities for 30 minutes.

Category

Treatment - Drugs

2

Description

Control group; Treated with the same method as intervention group ,but nasal tampons mixed with Normal Saline which remained in their intranasal cavities for 30 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr.Hashem Shemshadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation sciences

Full name of responsible person

Dr.hashem Shemshadi

Street address

Evin-Daneshjoo Blvd.Koodakyar St.

City

Tehran

Grant name

معاونت تحقیقات و فنا وری

Grant code / Reference number

91

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

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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

University of social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr.Hashem Shemshadi

Position

Associate professor/Plastic and Reconstructive Surgeon

Other areas of specialty/work

Person responsible for scientific inquiries

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University of Social Welfare and Rehabilitation sciences

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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