

# 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)

###### Phone

+98 21 2218 0140

###### Email address

shemshadi@uswr.ac.ir

##### 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

**Street address**

Evin-Daneshjoo Blvd.,Koodakyar St.

**City**

Tehran

**Street address**

Evin-Daneshjoo Blvd. Koodakyar St.

**City**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0140

**Fax**

+98 21 2218 0140

**Email**

shemshadi@uswr.ac.irshemshadii@gmail.comshemshadii@hotmail.com

**Web page address**

www.uswr.ac.ir/shemshadi

## 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

#### 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****Street address**

Evin-Daneshjoo Blvd.-Koodakyar st.

**City**

Tehran

**Postal code**

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**Phone**

+98 21 2218 0140

**Fax**

+98 21 2218 0140

**Email**

shemshadi@uswr.ac.ir shemshadii@gmail.com shemshadii@hotmail.com

**Web page address**

www.uswr.ac.ir/shemshadi

## Person responsible for updating data

#### 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

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**Email**

shemshadi@uswr.ac.irshemshadii@gmail.comshemshadii@hotmail.com

**Web page address**

www.uswr.ac.ir/shemshadi

**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*