Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Effect of local injection of botulinum toxin versus nasal fluticasone spray on clinical sign and symptoms in patients with allergic rhinitis: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of local injection of botulinum toxin versus nasal fluticasone spray on clinical sign and symptoms in patients with allergic rhinitis. Design: A triple blind randomized clinical trial. Setting and conduct: The eligible patients with allergic rhinitis who will refer to Besat Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 70 years; (b) having allergic rhinitis. Exclusion criteria: (a) pregnancy or breastfeeding; (b) contraindication of corticosteroids; (c) having severe anatomical abnormality in nose or acute rinosinusitis; (d) having glaucoma or prostatic hypertrophy; (e) having severe systemic diseases such as diabetes or asthma; (f) simultaneous using aminoglycoside drugs. Intervention group: Single dose injection of 50 unit Dysport dissolved in 0.1 ml normal saline in the frontal head of the inferior nasal turbinate in either side plus normal saline spray two puffs every 12 hours in either side of the nose for 8 weeks. Control group: Single dose injection of 0.1 ml normal saline in the frontal head of the inferior nasal turbinate in either side plus normal saline spray two puffs every 12 hours in either side of the nose for 8 weeks. Primary outcome: (a) assessing nasal congestion 8 weeks after intervention through physical examination; (b) assessing rhinorrhea 8 weeks after intervention through taking history; (c) assessing nasal itching 8 weeks after intervention through taking history; (b) assessing sneezing 8 weeks after intervention through taking history. Secondary outcome: Assessing dizziness 8 weeks after intervention through taking history.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506079014N67**

Registration date: **2015-06-16, 1394/03/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

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Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local injection of botulinum toxin versus nasal fluticasone spray on clinical sign and symptoms in patients with allergic rhinitis: a triple blind randomized clinical trial

Public title
Effect of local injection of botulinum toxin versus nasal fluticasone spray on clinical sign and symptoms in patients with allergic rhinitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: (a) age of 18 to 70 years; (b) having allergic rhinitis. Exclusion criteria: (a) pregnancy or breastfeeding; (b) contraindication of corticosteroids; (c) having severe anatomical abnormality in nose or acute rinosinusitis; (d) having glaucoma or prostatic hypertrophy; (e) having severe systemic diseases such as diabetes or asthma; (f) simultaneous using aminoglycoside drugs.
Age
From **8 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization of 4 group. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2015-05-26, 1394/03/05
Ethics committee reference number
IR.UMSHA.REC.1394.75

Health conditions studied

1

Description of health condition studied
Allergic rhinitis
ICD-10 code
J30.4
ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
assessing nasal congestion
Timepoint
8 weeks after intervention
Method of measurement
through physical examination

2

Description
assessing rhinorrhea
Timepoint
8 weeks after intervention
Method of measurement
through taking history

3

Description
assessing nasal itching
Timepoint
8 weeks after intervention
Method of measurement
through taking history

4

Description
assessing sneezing
Timepoint
8 weeks after intervention
Method of measurement
through taking history

Secondary outcomes

1

Description
Assessing dizziness
Timepoint
8 weeks after intervention
Method of measurement
through taking history

Intervention groups

1

Description
Single dose injection of 50 unit Dysport dissolved in 0.1 ml normal saline in the frontal head of the inferior nasal turbinate in either side plus normal saline spray two puffs every 12 hours in either side of the nose for 8 weeks.
Category
Treatment - Drugs

2

Description
Single dose injection of 0.1 ml normal saline in the frontal head of the inferior nasal turbinate in either side plus normal saline spray two puffs every 12 hours in either side of the nose for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Dr Somayeh damadi
Street address
Besat Hospital, Shahed Square.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
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 the Technology, Hamadan 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
Besat Hospital
Full name of responsible person
Dr Somayeh damadi
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Person responsible for updating data

Contact
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Department of Epidemiology
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Associate Professor
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