

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Clinical Trial of Comparison of Radiofrequency and Intranasal Corticosteroid Efficacies on Rhinomanometry, Symptom Severity, and Quality of Life in Patients With Inferior Turbinate Hypertrophy Due to Allergic Rhinitis

#### Protocol summary

##### Summary

This study is designed to assess the effects of radiofrequency and compares it with nasal corticosteroid spray in a 6-month follow-up. Ninety allergic rhinitis patients with inferior turbinate hypertrophy (ITH), referred to Baqiyatallah University of Medical Sciences Allergy Clinic will be enrolled to the study. Allergic rhinitis approves by clinical examination, history, and diagnostic tests such as rhinomanometry. Patients with other obstruction lesions, severe septal deviation, asthma, cigarette smoking, chronic rhino-sinusitis, history of other medical therapies, and history of sinus and nasal surgeries will be excluded. Patients will be randomized to radiofrequency (RF) and intranasal corticosteroid (INS) groups. Radiofrequency performs under local anesthesia with lidocaine 10% in three point of inferior turbinate two punctures in every points. (first point in front of inferior turbinate and parallel to septum, second point parallel to palmistry, and third point 2 cm posterior to other two points) The total dose of RF is 1500 joules (300 - 359 joules in each step). After procedure, patients will discharge immediately without any limitation in daily activities. For INS group Fluticasone 125 mcg intranasal spray will be prescribed twice a day and every time one puff in each side of the nose. Patients will be evaluated by rhinoscopy, symptoms (nasal obstruction, rhinorrhea, itchy nose, sneezing, caught, and facial pain) severity score (0-10 VAS score), rhinomanometry tests, and quality of life at first, third and sixth months after intervention. Collected data will be compared in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014042417413N1**

Registration date: **2014-05-08, 1393/02/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-05-08, 1393/02/18

##### Registrant information

###### Name

Hamidreza Karimi-Sari

###### Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8126 4354

###### Email address

hrkarimisari@bmsu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Baqiyatallah University of Medical Sciences, Deputy of Research.

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2014-02-20, 1392/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical Trial of Comparison of Radiofrequency and Intranasal Corticosteroid Efficacies on Rhinomanometry, Symptom Severity, and Quality of Life in Patients With Inferior Turbinate Hypertrophy Due to Allergic Rhinitis

## Public title

Comparison of the therapeutic Effect of Radiofrequency and Intranasal Corticosteroid in Patients with Inferior Turbinate Hypertrophy due to Allergic Rhinitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Allergic rhinitis patients with inferior turbinate hypertrophy referred to Baqiyatallah University of Medical Sciences Allergy Clinic without any age and gender limitations. Exclusion criteria: Patients with other obstruction lesions (e.g. polyp and tumor); severe septal deviation; asthma; cigarette smoking; chronic rhinosinusitis; history of other medical therapies; history of sinus and nasal surgeries

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah University of Medical Sciences Ethics Committee

##### Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

##### City

Tehran

##### Postal code

## Approval date

2014-01-05, 1392/10/15

## Ethics committee reference number

34-15

## 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

Rhinorrhea severity

#### Timepoint

Before treatment and one, three, and six months after intervention

#### Method of measurement

visual analogue score (0-10)

### 2

#### Description

Itchy nose severity

#### Timepoint

Before treatment and one, three, and six months after intervention

#### Method of measurement

visual analogue score (0-10)

### 3

#### Description

Nasal obstruction severity

#### Timepoint

Before treatment and one, three, and six months after intervention

#### Method of measurement

visual analogue score (0-10)

### 4

#### Description

Facial pain severity

#### Timepoint

Before treatment and one, three, and six months after intervention

#### Method of measurement

visual analogue score (0-10)

### 5

#### Description

Nasal airflow

**Timepoint**

Before treatment and one, three, and six months after intervention

**Method of measurement**

Rhinomanometry

**6****Description**

Quality of life

**Timepoint**

Before treatment and one, three, and six months after intervention

**Method of measurement**

Rhino-conjunctivitis quality of life questionnaire (RQLQ)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Radiofrequency of inferior turbinate under local anesthesia with lidocaine 10% in three point of inferior turbinate (first point in front of inferior turbinate and parallel to septum, second point parallel to palmistry, and third point 2 cm posterior to other two points), two punctures in every points, with the total dose of 1500 ± 200 joules (300 - 359 joules in each step)

**Category**

Treatment - Surgery

**2****Description**

Fluticasone 125 mcg intranasal spray, twice a day and every time one puff in each side of the nose

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Baqiyatallah University of Medical Sciences Polyclinic

**Full name of responsible person**

Hamidreza Karimi Sari

**Street address**

Baqiyatallah University of Medical Sciences Polyclinic, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Baqiyatallah University of Medical Sciences, Deputy of Research

**Full name of responsible person**

Hamidreza Zangeneh

**Street address**

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Baqiyatallah University of Medical Sciences, Deputy of Research

**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**

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran

**Full name of responsible person**

Hamidreza Karimi Sari

**Position**

General Practitioner

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Department of ENT, Baqiyatallah University of Medical Sciences, Tehran, Iran

**Full name of responsible person**

Abolfazl Taheri

**Position**

Assistant Professor

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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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*