

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Assessment of the Effect of Endoscopic Sinus Surgery on Olfactory Threshold of Patients with Chronic Rhinosinusitis without Nasal Polyps; A Randomized Clinical Trial

#### Protocol summary

##### Summary

This randomized clinical trial was conducted at Baqiyatallah University hospital, Tehran, Iran for evaluating the effect of endoscopic sinus surgery on quality of olfaction in patients with chronic rhinosinusitis. A total of 30 patients with chronic rhinosinusitis without nasal polyps were needed for this trial. Patients between 18 and 65 years of age who had not responded to standard medical treatment with nasal irrigation by normal saline (4 times daily), nasal corticosteroid Fluticasone (one puff daily) and antibiotic therapy by Cefixime (400 mg daily) for 4 weeks, were enrolled in the trial. Patients with history of head trauma or smoking and those who were using olfaction-affecting drugs were excluded from the study. A written informed consent was obtained from all patients. Demographic information as well as drug, trauma and smoking history were recorded in a predesigned checklist. Patients were randomly allocated to two intervention and control groups using random number table; patients in intervention group underwent endoscopic sinus surgery by a single surgeon and olfactory threshold was evaluated using smell threshold test (STT) before, one month and three months after surgery based on Pennsylvania University manual. Patients in control group continued standard treatment with nasal irrigation of normal saline (4 times daily) and nasal corticosteroids (one puff daily) and olfactory threshold using STT at baseline, one and three months after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017050517413N24**

Registration date: **2017-06-23, 1396/04/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-23, 1396/04/02

##### 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

Vice chancellor for research, Baqiyatallah University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of the Effect of Endoscopic Sinus Surgery on Olfactory Threshold of Patients with Chronic Rhinosinusitis without Nasal Polyps; A Randomized Clinical Trial

## Public title

The effect of endoscopic sinus surgery on improvement of olfaction in chronic rhinosinusitis patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Patients between 18 and 65 years of age; no response to standard medical treatment with nasal irrigation by normal saline (4 times daily), nasal corticosteroid Fluticasone (one puff daily) and antibiotic therapy by Cefixime (400 mg daily) for 4 weeks Exclusion criteria: Head trauma; Smoking; prior other treatments

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## 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 randomly allocated to two intervention and control groups using random number table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

##### Street address

Nosrati ave., South Sheykh Bahaei, Mollasadra st., Vanaq sq., Tehran

##### City

Tehran

##### Postal code

#### Approval date

2016-04-10, 1395/01/22

#### Ethics committee reference number

IR.BMSU.REC.1395.10

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Rhinosinusitis

#### ICD-10 code

J31.0, J32

#### ICD-10 code description

Chronic Rhinitis, Chronic Sinusitis

## Primary outcomes

### 1

#### Description

Olfactory threshold

#### Timepoint

Before, one month and three months after intervention

#### Method of measurement

Smell Threshold Test

## Secondary outcomes

### 1

#### Description

Drug Complications

#### Timepoint

During study

#### Method of measurement

Patients' complaint

### 2

#### Description

Surgical Complications

#### Timepoint

After surgery

#### Method of measurement

Examination and patients' complaints

## Intervention groups

### 1

#### Description

Intervention group: Endoscopic Sinus Surgery

#### Category

Treatment - Surgery

### 2

#### Description

Control group: nasal irrigation of normal saline (4 times daily) and nasal corticosteroids fluticasone (one puff daily) for three months

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Mohammad Hossein Khosravi

**Street address**

Hafez, Jomhouri st., Tehran

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**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Morteza Izadi

**Street address**

Baqiyatallah University of Medical Sciences, Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq., Tehran, Iran

**City**

Tehran

**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, Baqiyatallah 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**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Morteza Izadi

**Position**

Vice Chancellour for research

**Other areas of specialty/work**

**Street address**

Nosrati Alley, Sheykh Bahaei st, Mollasadra st., Vanaq

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Department of Otorhinolaryngology, Head and Neck Surgery, Faculty of Medicine, Baqiyatallah Universi

**Full name of responsible person**

Jaleh Yusefi

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Otolaryngologist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Student Research Committee, Baqiyatallah University of medical sciences, Tehran, Iran.

**Full name of responsible person**

Mohammad Hossein Khosravi

**Position**

Secretary-General

**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*