

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

City

Tehran

sq., Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 8862 0826

Fax

Email

pr@bmsu.ac.ir

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

Position

Otolaryngologist

Other areas of specialty/work

Street address

Nosrati Alley, Sheykh Bahaei st, Mollasadra st., Vanaq sq., Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 8862 0826

Fax

Email

yousefi.jaleh@gmail.com

Web page address

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

Street address

Nosrati Alley, Sheykh Bahaei st., Mollasadra st., Vanaq sq., Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 8862 0826

Fax

Email

dr.mhkhosravi@gmail.com

Web page address

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