Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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 Pensylvania 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

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Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

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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 interventin
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
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Hafez, Jomhouri st., Tehran
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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
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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

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Person responsible for updating data

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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