

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparative study of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and rhinoplasty with or without "Tongue In Groove" technique in patients undergoing Endoscopic Sinus Surgery

#### Protocol summary

##### Summary

Comparison of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and Rhinoplasty with or without "Tongue In Groove" technique . This study is randomised, not blinded, without placebo, interventional and will done with 45 chronic rhinosinusitis patients undergoing rhinoplasty divided in 3 groups of 15 individuals. The first group will be treated by endoscopic sinus surgery alone. The second group will be treated by Concurrent Endoscopic Sinus Surgery and Rhinoplasty with "Tongue In Groove" technique and the third group will be treated by Concurrent Endoscopic Sinus Surgery and Rhinoplasty without "Tongue In Groove" technique. Inclusion criteria: CRS with or without nasal polyps; no Response to medical treatment; age 15 - 60 Exclusion criteria: Acute infection; Failure to complete medical treatment; immune system disorders; systemic disorders like hypertension, diabetes mellitus, chronic kidney disease and malignancy; pregnancy All three groups will undergo surgery. Patients before surgery and 1, 3 and 6 months after surgery will be evaluated in terms of the width of the middle meatus, edema of the nasal mucosa, Lund Kennedy score in endoscopy, patient satisfaction from the nose, surgeon satisfaction of the nose, difficulty breathing, nasal congestion. The intraoperative blood loss and the duration of surgery will be recorded. Recurrent nasal polyps in the examination 1, 3 and 6 months after surgery will be discussed. Finally, the data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051128006N1**

Registration date: **2017-07-13, 1396/04/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-13, 1396/04/22

##### Registrant information

###### Name

Mohamad Sadeghi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6658 1628

###### Email address

sadeghi@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2016-08-22, 1395/06/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of the results of endoscopic sinus surgery and Concurrent Endoscopic Sinus Surgery and rhinoplasty with or without "Tongue In Groove" technique in patients undergoing Endoscopic Sinus Surgery

IR.TUMS.VCR.REC.1395.348

## Health conditions studied

### 1

#### Description of health condition studied

Chronic rhinosinusitis with or without polyposis

#### ICD-10 code

J32

#### ICD-10 code description

Chronic sinusitis

## Primary outcomes

### 1

#### Description

Edema of the nasal mucosa

#### Timepoint

One day before surgery and 1, 3 and 6 months after that

#### Method of measurement

Nasal Endoscopy

### 2

#### Description

The width of the middle meatus

#### Timepoint

One day before surgery and 1, 3 and 6 months after that

#### Method of measurement

Clinical examination and Nasal Endoscopy

### 3

#### Description

Endoscopic assessment of the nose

#### Timepoint

One day before surgery and 1, 3 and 6 months after that

#### Method of measurement

Nasal endoscopy by the Lund Kennedy scoring system

### 4

#### Description

Patient satisfaction from the nose

#### Timepoint

One day before surgery and 1, 3 and 6 months after that

#### Method of measurement

Questionnaire

### 5

#### Description

Surgeon satisfaction of the nose

#### Timepoint

One day before surgery and 1, 3 and 6 months after that

#### Method of measurement

Questionnaire

## Public title

Comparing two surgical procedures for Sinusitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: CRS with or without nasal polyps; no Response to medical treatment; age 15 - 60 Exclusion criteria: Acute infection; Failure to complete medical treatment; immune system disorders; systemic disorders like hypertension, diabetes mellitus, chronic kidney disease and malignancy; pregnancy

## Age

From **15 years** old to **60 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **45**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomization for three interventional groups will done by balanced blocks.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Tehran/ Keshavarz s./ 16azar s./ Tehran university of medical sciences

##### City

Tehran

##### Postal code

#### Approval date

2016-07-24, 1395/05/03

#### Ethics committee reference number

## **6**

### **Description**

Difficulty breathing

### **Timepoint**

One day before surgery and 1, 3 and 6 months after that

### **Method of measurement**

Questionnaire

## **Secondary outcomes**

## **1**

### **Description**

The duration of surgery

### **Timepoint**

Intraoperative

### **Method of measurement**

The report surgery

## **2**

### **Description**

Blood lost during surgery

### **Timepoint**

Intraoperative

### **Method of measurement**

Questionnaire

## **3**

### **Description**

Recurrent nasal polyps

### **Timepoint**

1,3 and 6 months after surgery

### **Method of measurement**

Nasal endoscopy

## **4**

### **Description**

Nasal congestion

### **Timepoint**

One day before surgery and after that

### **Method of measurement**

Questionnaire

## **Intervention groups**

## **1**

### **Description**

Interventional group 1: Endoscopic sinus surgery alone

### **Category**

Treatment - Surgery

## **2**

### **Description**

Intervention group 2: Endoscopic sinus surgery and rhinoplasty at the same time, with "Tongue In Groove" Technique

### **Category**

Treatment - Surgery

## **3**

### **Description**

Intervention group 3: Endoscopic sinus surgery and rhinoplasty at the same time, without "Tongue In Groove" Technique.

### **Category**

Treatment - Surgery

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Emam Khomeini hospital

#### **Full name of responsible person**

Fateme Tavakolnejad

#### **Street address**

ENT department, Emam Khomeini hospital, Keshavarz st, Tehran

#### **City**

Tehran

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences, Vice chancellor for research

#### **Full name of responsible person**

Masud Yunesian

#### **Street address**

Office building of Tehran University of Medical Sciences, Keshavarz s., Tehran

#### **City**

Tehran

#### **Grant name**

-

#### **Grant code / Reference number**

-

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tehran University of Medical Sciences, Vice chancellor for 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Fateme Tavakolnejad

**Position**

Assistant ENT

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

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## Person responsible for scientific inquiries

### Contact

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Mmohamad Sadeghi

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Faculty member of ENT departmenr

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## Person responsible for updating data

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**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*