

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of satisfaction and bleeding of Triamcinolone impregnated gelfoam with Triamcinolone impregnated Surgicel in nasal dressing after endoscopic sinus surgery in patients with polyposis

#### Protocol summary

2018-08-11, 1397/05/20

#### Study aim

Comparison of satisfaction and bleeding of Triamcinolone impregnated gelfoam with Triamcinolone impregnated Surgicel in nasal dressing after endoscopic sinus surgery in patients with polyposis.

#### Design

a randomized, double blinded, controlled clinical trial

#### Settings and conduct

Amiralam hospital, endoscopic sinus surgery

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age between 18-65 years 2- Bilateral polyposis 3- Diagnosis of chronic rhinosinusitis based on EPOS 2012. 4-Chronic rhinosinusitis resistant to medical therapy Exclusion criteria: 1.Any systemic or rheumatologic diseases related to nasal disorders like cystic fibrosis, wegner, sarcoidosis 2.Other pathologies than polyposis such as inverted papilloma or neoplasms

#### Intervention groups

One group of patients with chronic rhinosinusitis with bilateral polyposis received Triamcinolone impregnated gelfoam as a nasal dressing and other group received Triamcinolone impregnated Surgicel as a nasal dressing.

#### Main outcome variables

The rate of satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150907023936N2**

Registration date: **2018-08-11, 1397/05/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-11, 1397/05/20**

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Mohsen Naraghi

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8888 1376

##### Email address

naraghim@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-04-04, 1397/01/15

#### Expected recruitment end date

2020-04-03, 1399/01/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of satisfaction and bleeding of Triamcinolone impregnated gelfoam with Triamcinolone impregnated Surgicel in nasal dressing after endoscopic sinus surgery in patients with polyposis

#### Public title

Comparison of endoscopic findings of Triamcinolone impregnated gelfoam with Triamcinolone impregnated Surgicel in nasal dressing after endoscopic sinus surgery in patients with polyposis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 18 to 65 years old Bilateral polyposis Diagnosis of chronic rhinosinusitis based on EPOS 2012 Chronic rhinosinusitis resistant to medical therapy

### Exclusion criteria:

Any systemic or rheumatologic diseases related to nasal disorders like cystic fibrosis, Wegener, sarcoidosis Other pathologies than polyposis such as inverted papilloma or neoplasms

## Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyst

## Sample size

Target sample size: **23**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each side of nose will be assessed as an intervention group

## Randomization (investigator's opinion)

Randomized

## Randomization description

Computer assisted random allocation

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Post operative assessment about patient complaints, will be done by a resident or fellowship resident who is blind to the type of dressing. Also, the patients themselves are also blind about the dressing's type.

## Placebo

Not used

## Assignment

Parallel

## Other design features

In included patients Lund-Mackay and Lund-Kennedy score will be assessed pre-operatively. All the patients will be operated by one surgeon. Randomly, one side of the nose will be dressed with Triamcinolone impregnated gelfoam and the other will be dressed by Triamcinolone impregnated Surgicel. The post operative assessment about patient complaints, will be done by a resident or fellowship resident who is blind to the type of dressing.

## Secondary IDs

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

#### Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

#### Approval date

2018-02-25, 1396/12/06

#### Ethics committee reference number

IR.TUMS.VCR.REC.1396.4630

## Health conditions studied

## 1

### Description of health condition studied

chronic rhinosinusitis with polyposis

#### ICD-10 code

J33

#### ICD-10 code description

Nasal polyp

## Primary outcomes

## 1

### Description

satisfaction

### Timepoint

1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months

### Method of measurement

likert

## Secondary outcomes

## 1

### Description

bleeding

### Timepoint

1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months

### Method of measurement

likert

## Intervention groups

## 1

### Description

Intervention group: Triamcinolone impregnated gelfoam nasal dressing

### Category

Treatment - Devices

**2**

**Description**

Control group: Triamcinolone impregnated surgical nasal dressing

**Category**

Treatment - Devices

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

AmirAlam hospital

**Full name of responsible person**

Dr Shirin Irani

**Street address**

AmirAlam hospital, North Saadi Ave

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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resdeputy@tums.ac.ir

**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

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr shirin Irani

**Position**

Otorhinolaryngologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Contact**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Full name of responsible person**

Dr Shirin Irani

**Position**

Otorhinolaryngologist

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available