

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 analyser

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Email

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