Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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 reheumatologic 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
2018-08-11, 1397/05/20

Registrant information

Name
Mohsen Naraghi

Name of organization / entity
Tehran University of Medical Science

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Iran (Islamic Republic of)

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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 reheumatologic diseases related to nasal disorders like cystic fibrosis, wegner, 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 well be dressed with Triamcinolone impregnated gelfoam and the other will be dressed by Triamcinolone impregnated Surgicel. The post operative assessment about patient complaints, will 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
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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, 3months, 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 surgicel 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
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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
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Contact

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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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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