Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effectiveness of intranasal PRF treatment compared to standard treatment on mucosal healing at the cautery site during rhinosinusitis endoscopic surgery in chronic rhinosinusitis patients referred to Taleghani Hospital during 1403-1405

Protocol summary

Study aim
Determining and comparing the effectiveness of intranasal platelet-rich fibrin (PRF) treatment with standard treatment on mucosal healing at the cautery site during FESS surgery in chronic sinusitis patients

Design
The method of randomizing the nasal cavity of the patients in two groups will be block. There are 61 people in this study

Settings and conduct
during FESS surgery in chronic rhinosinusitis patients referred to Taleghani Hospital during 1403-1405

Participants/Inclusion and exclusion criteria
Age between 18 and 60 years, bilateral chronic rhinosinusitis with nasal polyps, and difference in scores of two or less LUND MACKY SCORE between both nostrils. Patients with unilateral nasal polyps, enterocean polyps, chronic rhinosinusitis without polyps, a history of nasal or sinus surgery, and chronic disorders and immunodeficiencies that impair wound healing will not be included in this study.

Intervention groups
In this study, all adult patients over 18 years of age suffering from chronic rhinosinusitis undergoing FESS surgery who referred to Taleghani Hospital from 1403 to 1405 will be examined. In this study, patients for whom electrocautery is used in two nasal cavities during FESS surgery, platelet-rich fibrin (PRF) is prepared using the patient's own venous blood, and randomly placed in one of the nasal cavities at the cautery site. is given and the other cavity of the nose is repaired in a standard way, and this cavity is considered as the control group. Then both cavities under the endoscopic guide are homeostasised and packed in the same way. The cautery device is the same for all patients and the intensity is 20 degrees and bipolar cautery is used.

Main outcome variables
Helping to treat early mucosal destruction and reduce the recurrence of the disease

General information

Reason for update

Acronym
PRF

IRCT registration information
IRCT registration number: **IRCT20240518061832N1**
Registration date: **2024-10-17, 1403/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-17, 1403/07/26**
Update count: **0**

Registration date
2024-10-17, 1403/07/26

Registrant information

Name
vahid Ghasem amooeian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 991 915 3531

Email address
vahidvm2m@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-06, 1403/07/15

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of intranasal PRF treatment compared to standard treatment on mucosal healing at the cautery site during rhinosinusitis endoscopic surgery in chronic rhinosinusitis patients referred to Taleghani Hospital during 1403-1405

Public title

Investigating the effectiveness of intranasal PRF treatment compared to standard treatment on mucosal healing at the cautery site during rhinosinusitis endoscopic surgery in chronic rhinosinusitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Bilateral chronic rhinosinusitis with nasal polyps A difference in scores of two or less LUND MACKY SCORE between both nasal cavities Age between 18 and 60 years

Exclusion criteria:

Patients with unilateral nasal polyps antrochoanal polyp Chronic rhinosinusitis without polyps History of nose or sinus surgery Immunity deficiency

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

For simple randomization, the number table of Rand company's program is used, and a plan is given for intervention in each of the donor nasal cavities by the operator, and one of the cavities is randomly selected as the intervention group, and fibrin rich in platelets is included in it. The hole is placed. Also, the other hole is determined as a sample and control group. All this information is recorded by the project manager, and in order not to affect the surgical procedure, the surgeon is not informed until the end of the operation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

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Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Province

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Postal code

1985717443

Approval date

2024-09-18, 1403/06/28

Ethics committee reference number

IR.SBMU.MSP.REC.1403.356

Health conditions studied

1

Description of health condition studied

Chronic sinusitis after endoscopic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determining and comparing the effectiveness of intranasal platelet-rich fibrin (PRF) treatment with standard treatment on wound healing at the cautery site during FESS surgery in chronic sinusitis patients

Timepoint

Patients 3 days after surgery and after removing tampons if any and two weeks after surgery and one month after surgery and three months after surgery in terms of shortness of breath and bleeding and endoscopic findings in terms of adhesion and wound healing and site Wounds and cautery are checked.

Method of measurement

Accordingly, the following were scored by endoscopic assessment: Adhesion (0 = none, 1 = adhesion not affecting sinus drainage, 2 = moderate adhesion affecting sinus drainage, 3 = complete adhesion between the middle and lateral prongs of the nasal wall (bleeding) 0 = none; 1 = minimal, confined to nasal cavity; 3 = severe, need for cauterization (0 = minimal, 2 = moderate, 3 = severe) (0) = no infection, 1 = mild purulent mucous discharge, 2 = moderate purulent

mucous discharge, 3 = severe purulent mucous discharge) granulation (0 = none, 1 = minimal, 2 = moderate, 3 = severe) also from patient questionnaire NOSE and history are taken before and after surgery and during the follow-up period. Finally, all the information is collected and then the statistical analysis of the data is done.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, all adult patients over 18 years of age suffering from chronic rhinosinusitis undergoing FESS surgery who referred to Taleghani Hospital from 1403 to 1405 will be examined. In this study, patients for whom electrocautery is used in two nasal cavities during FESS surgery, platelet-rich fibrin (PRF) is prepared using the patient's own venous blood, and randomly placed in one of the nasal cavities at the cautery site.

Category
Treatment - Surgery

2

Description
Control group: After one of the patient's nasal cavities was randomly selected for intervention. The other cavity of the nose is repaired in a standard way, and this cavity is considered as the control group. Then both cavities under the endoscopic guide are homeostasised and packed in the same way. With this method, the control group and the intervention are performed on one patient, which creates a better matching for this plan.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
patients referred to Taleghani Hospital during 1403-1405

Full name of responsible person
vahid ghasem amooeian

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Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Research Assistant, Shahid Beheshti University of Medical Sciences, Tehran

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Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
vahid ghasem amooeian

Position
ENT resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Patient information remains confidential, but results are shared with privacy and data protection

When the data will become available and for how long
always

To whom data/document is available
everyone

Under which criteria data/document could be used
All items

From where data/document is obtainable
Email of the responsible person

What processes are involved for a request to access data/document
Contact by phone or email

Comments