Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

comparing the effects of injecting a mixture of corticosteroids and platelet-rich plasma in the olfactory cleft of patients with nasal polyposis on the improvement of anosemia after endoscopic sinus surgery and comparing it with placebo.

Protocol summary

Study aim
The study of the effect of platelet-rich plasma and corticostroid injection on olfactory outcomes following endoscopic sinus surgery in patients with nasal polyps.

Design
A randomized, parallel-group, controlled clinical trial with two groups, involving a total of 40 patients. Block randomization with blocks of four was used for randomization.

Settings and conduct
In the intervention group, 1 milliliter of platelet-rich plasma (PRP) and 1cc of triamcinolon will be injected intranasally. The PRP will be injected using a 1cc syringe with a 30-gauge needle into the olfactory regionunder endoscopic visualization, and performed by a physician. In the control group, 1cc of normal saline will be injected into the same area. Patients will be blinded to their group allocation and the type of intervention performed and will be under general anesthesia during injection. Preoperative and 6-month postoperative assessments will be performed by the same physician using the I-SIT olfactory scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 15 to 50 years with nasal polyps, having varying degrees of olfactory dysfunction based on the Iran olfactory identification test score, and with a duration of anosmia of less than 2 years. Exclusion criteria: A history of head trauma, previous sinonasal surgery, smoking, congenital anosmia, and the presence of systemic disorder, Additionally, patients with missing data or those lost to follow-up will also be excluded from the study.

Intervention groups
In the intervention group, platelet-rich plasma and corticostroid injection will be administered to patients with polyposis during endoscopic sinus surgery. In the comparison group, normal saline injection was performed in patients with polyposis during endoscopic sinus surgery.

Main outcome variables
olfactory changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230127057244N2**
Registration date: **2024-12-27, 1403/10/07**
Registration timing: **prospective**

Last update: **2024-12-27, 1403/10/07**
Update count: **0**

Registration date
2024-12-27, 1403/10/07

Registrant information

Name
Mohammadreza Firouzifar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6670 3037

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2026-01-21, 1404/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparing the effects of injecting a mixture of corticosteroids and platelet-rich plasma in the olfactory cleft of patients with nasal polyposis on the improvement of anosemia after endoscopic sinus surgery and comparing it with placebo.

Public title
comparing the Effect of corticosteroids and PRP on anosemia with placebo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Nasal polyposis , Having different severities of olfactory disorder based on the olfactory recognition test score and duration of anosmia less than 2 years.
Exclusion criteria:
Head trauma Prior sinus surgery Somking more than 20 pack:year in last year Systemic disease like parkinsone and alzheimer DRAF3 or 2b
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation of patients into two groups is done by the stratified block randomization method. In such a way that first the eligible patients are referred in the order of entry They are classified according to age and sex. Then based on blocks of 4 (consisting of two groups A and B and two repetitions for each) that are randomly selected from among all the possible cases of permutations and assigned to the desired group they find These blocks were created using the statistical software R version 4.0.2.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients participating in the project will be blinded to receiving medicine or placebo.the injection will be done during general anestesia
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Vice Chancellor for Research and Technology, Ghods St., Keshavarz Blvd
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Tehran
Province
Tehran
Postal code
1417653761
Approval date
2024-06-30, 1403/04/10
Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1403.012

Health conditions studied

1

Description of health condition studied
Chronic Sinusitis
ICD-10 code
J32.4
ICD-10 code description
Chronic pansinusitis

Primary outcomes

1

Description
Olfactory Outcomes
Timepoint
before intervention and 6 month after
Method of measurement
I_SIT Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Injection of a mixture of one cc platelet-rich plasma solution obtained from centrifugation of patients' blood samples and in one cc triamcinolone from Iran Hormon Pharmaceutical Company in the olfactory cleft area of the patients in a space of one centimeter in patients with chronic sinusitis with polyps who have undergone endoscopic sinus surgery. This procedure will be performed at the end of the surgery and will not be repeated.

Category

Treatment - Drugs

2

Description

Control group: Injecting one cc of normal saline from Iran Injectable and Pharmaceutical Products Company following endoscopic sinus surgery in the olfactory cleft area of patients in a space of one centimeter in patients with chronic sinusitis with polyps who have undergone endoscopic sinus surgery. This procedure will be performed at the end of the surgery and will not be repeated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Alam hospital ENT clinic

Full name of responsible person
Amirmohamad Behrang

Street address
Amir Alam hospital ENT clinic, North Sadi St., Enghelsb Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

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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

2

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
MohammadReza Firozifar

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Amir Alam hospital ENT clinic, North Saadi St., Enghelsb 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

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
MohammadReza Firozifar
Position
Assistant professor
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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Person responsible for updating data

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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