Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

A comparative randomized study of injecting platelet-rich plasma solution versus normal saline injection on olfactory outcomes following endoscopic sinus surgery in patients with chronic sinusitis accompanied by nasal polyps : a single-center clinical trial

Protocol summary

Study aim
The study of the effect of platelet-rich plasma injection on olfactory outcomes following endoscopic sinus surgery in patients with chronic sinusitis with 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) will be injected intranasally. The PRP will be injected using a 1cc syringe with a 30-gauge needle into the olfactory region, covering an area of 1 square centimeter, under 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. The data collector will also be blinded to both the group allocation and the injected substance. Additionally, the individual responsible for data collection will not be present during the injection procedure. 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 injection will be administered to patients with polyposis during endoscopic sinus surgery.

Main outcome variables
Improvement of olfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230127057244N3**
Registration date: **2024-12-29, 1403/10/09**
Registration timing: **prospective**

Last update: **2024-12-29, 1403/10/09**
Update count: **0**

Registration date
2024-12-29, 1403/10/09

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
2025-11-22, 1404/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative randomized study of injecting platelet-rich plasma solution versus normal saline injection on olfactory outcomes following endoscopic sinus surgery in patients with chronic sinusitis accompanied by nasal polyps : a single-center clinical trial

Public title
A comparative study of injecting platelet-rich plasma solution versus normal saline injection on olfactory outcomes following endoscopic sinus surgery in patients with chronic sinusitis accompanied by nasal polyps.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 15 to 50 years with nasal polyps. Having different severities of olfactory disorder based on the olfactory recognition test score and duration of anosmia less than 2 years.
Exclusion criteria:
Head Truma Revision Sinonasal Surgery Smoking Congenital Anosmia Systemic Disorder
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
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
In this study, a single-blind method is used. This means that the patient is aware of their participation in the study but will not be informed about the type of intervention, whether it is normal saline or platelet-rich plasma. However, the physician and the principal investigator are aware of the type of injected substance and the selected individuals.
Placebo
Not 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
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2024-04-20, 1403/02/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.008

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
At entrance time to trial and 6 months later
Method of measurement
Sino-nasal Outcome Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of platelet-rich plasma solution on olfactory outcome after endoscopic sinus surgery in sick patients to chronic sinusitis with polyps
Category
Treatment - Drugs

2

Description
Control group: Normal saline injection on olfactory outcome following endoscopic sinus surgery in patients with chronic sinusitis with polyps.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Alam hospital ENT clinic
Full name of responsible person
Mahnaz Darvishzade Yazdi
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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
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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
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Street address
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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 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