

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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)

Phone

+98 21 6670 3037

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mrfirouzifar@sina.tums.ac.ir

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

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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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 updating data

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Fax

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