

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 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 anosmia after endoscopic sinus surgery and comparing it with placebo.

Protocol summary

Study aim

The study of the effect of platelet-rich plasma and corticosteroid 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 region 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 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 corticosteroid 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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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 anosmia after endoscopic sinus surgery and comparing it with placebo.

Public title

comparing the Effect of corticosteroids and PRP on anosmia 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 Smoking more than 20 pack:year in last year Systemic disease like parkinsons 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 anesthesia

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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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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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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

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Person responsible for general inquiries

Contact

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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