

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation the effectiveness of platelet-rich plasma in smell Improvement of Patients with nasal polyposis due to chronic sinusitis

#### Protocol summary

##### Study aim

Platelet-rich plasma efficacy in improving olfactory odor in patients with sinusoidal polyposis

##### Design

Clinical trial, randomized block allocation method by quota method to two parallel groups of 27 patients, Double-blind

##### Settings and conduct

Sampling was available type among those who referred to the ENT clinic of Taleghani Hospital in Tehran. Platelet-rich plasma was injected into the intervention group after endoscopic sinus surgery in the operating room and under general anesthesia. The patients were unaware of the type of intervention performed during anesthesia and the technician who evaluates the outcome was not present during the surgical procedure.

##### Participants/Inclusion and exclusion criteria

Study entry requirements: \_15 to 50 years old \_Having chronic sinusitis with polyps \_Anosmia or Hyposmia confirmed by olfactory testing \_Anosmic duration less than 2 years Conditions for not entering the study: \_History of head injuries \_History of previous sinus surgery \_Smoking \_Congenital anosmia \_Systemic diseases

##### Intervention groups

Patients with polyposis with hyposmia were treated with oral corticosteroids for 5 days. Patients were then divided into two groups: intervention and control. In each group, the quota was based on the severity of the polyposis. Patients in both groups underwent functional endoscopic sinus surgery by only one specific ENT specialist. At this stage, in the intervention group, platelet-rich plasma and In the control group, the Normal saline serum was injected into the patient's olfactory mucosa inside the operating room and during general anesthesia. Smell test score in all patients before any intervention and endoscopic sinus surgery and 3 months after surgery with Smell diagnosis test was performed by a technician and the results were recorded. Then the scores of the

Smell test were compared in both groups.

##### Main outcome variables

Smell test score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200211046464N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

##### Registration date

2020-05-04, 1399/02/15

##### Registrant information

##### Name

Mehdi Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4483 3279

##### Email address

mohammady\_md@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

2017-09-23, 1396/07/01

##### Actual recruitment end date

2019-09-23, 1398/07/01

**Trial completion date**

2019-09-23, 1398/07/01

**Scientific title**

Evaluation the effectiveness of platelet-rich plasma in smell Improvement of Patients with nasal polyposis due to chronic sinusitis

**Public title**

Effect of PRP in treatment of anosmia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 15 and 50 years Having chronic sinusitis with polyps Anosmia lasts less than 2 years Existence of anosmia confirmed by olfactory diagnosis test

**Exclusion criteria:**

Suffering from systemic diseases such as diabetes mellitus, Parkinson's and Alzheimer's smoking Head injury history Previous surgical history of paranasal sinuses Congenital anosmia

**Age**

From **15 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **24**

Actual sample size reached: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block Random assignment

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients are unaware of the type of intervention performed during general anesthesia and the technician who evaluates the outcome is not present during the surgical procedure. Surgeon in charge of injection.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Iran National committee for Ethics in Biomedical Research

**Street address**

floor 2., No. 11, Mohammadi Rd., East Kourosh St., North Janat Abad Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1477835814

**Approval date**

2019-04-23, 1398/02/03

**Ethics committee reference number**

IR.SBMU.MSP.REC.1398.011

**Health conditions studied**

**1**

**Description of health condition studied**

Nasal Polyp

**ICD-10 code**

J33

**ICD-10 code description**

Nasal polyp

**2**

**Description of health condition studied**

Anosmia

**ICD-10 code**

R43.0

**ICD-10 code description**

Anosmia

**Primary outcomes**

**1**

**Description**

Olfactory score less than 6 in the Iranian Smell Identification Test

**Timepoint**

Measurement of olfactory score at the beginning of the study (before the intervention), After receiving oral treatment and 3 months after surgery and injection of platelet-rich plasma

**Method of measurement**

Iranian Smell Identification Test

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Patients in both groups underwent sinus endoscopic surgery by only one specific ENT specialist. At this stage, in the intervention group, a platelet-rich plasma was injected into the patient's nose inside the operating room and during general anesthesia. To do this, platelet-rich plasma was injected with a 1 cc syringe in the olfactory area within 1 cm<sup>2</sup> with the help of a nasal endoscope and by the same surgeon from specific ENT specialists. The whole process of preparing platelet-rich plasma was performed in the sports medicine group under the supervision of the sports medicine professor and using Arjangian platelet-rich plasma kits. The temperature during these steps to prevent plaque clots was 21-24. C.

### Category

Treatment - Other

## 2

### Description

Control group: After Functional endoscopic sinus surgery, in the control group, instead of platelet-rich plasma, normal saline serum was injected into the patient's olfactory area with the same amount and under the same conditions. The injector was also unaware of the group of patients and the injected substance.

### Category

Treatment - Surgery

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Taleghani Hospital

#### Full name of responsible person

Mehdi Mohammadi

#### Street address

ENT Department., Taleghani Hospital., Next to Shahid Beheshti University of Medical Sciences., Shahid Arabi St., Yemen St., Shahid Chamran Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1985711151

#### Phone

+98 21 2303 1111

#### Fax

+98 21 2243 2570

#### Email

Taleghanihospital@sbmu.ac.ir

#### Web page address

<http://taleghani.sbmu.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

Deputy of Research and Technology., 5th Floor., Headquarters Building 2., Shahid Beheshti University of Medical Sciences and Health Services., Next to Taleghani Hospital., Shahid Abbas Aarabi St., (Parvaneh)., Shahid Arabi St., Yemen St., Shahid Chamran Highway

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#### Postal code

1985711151

#### Phone

+98 21 2243 9780

#### Fax

+98 21 2243 9981

#### Email

Mpajouhesh@sbmu.ac.ir

#### Web page address

<https://retech.sbmu.ac.ir>

### 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

Mehdi Mohammadi

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Ear, Nose, and Throat

#### Street address

floor 2., No. 11, Mohammadi Rd., East Kourosh St., North Janat Abad Blvd

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**Phone**

+98 21 4483 3279

**Email**

Dr.md.mohammadi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ali Goljanian Tabrizi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Rhinology

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**Email**

ali.goljanian@gmail.com

**Web page address**<http://taleghani.sbmu.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahboobeh Asadi Amiri

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

ENT Department., Taleghani Hospital., Next to Shahid Beheshti University of Medical Sciences., Shahid Arabi St., Yemen St., Shahid Chamran Highway

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1985711151

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**Email**

Mahboobeh\_farvardin@yahoo.com

**Web page address**<http://taleghani.sbmu.ac.ir>**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**

Information about the main outcome after not identifying individuals

**When the data will become available and for how long**

6 months after printing the results

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Scientific research in academic institutions

**From where data/document is obtainable**Ali Goljanian Tabrizi; Ali.goljanian@gmail.com  
Mahboobeh Asadi Amiri;  
Mahboobeh\_farvardin@yahoo.com**What processes are involved for a request to access data/document**

State the name, academic or professional rank, the applicant center and the reason for the application in your email. Files and documents will be sent about 1 month after the request is processed.

**Comments**