Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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

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Iran (Islamic Republic of)

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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

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

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Province

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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 cm2 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

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

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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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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

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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