

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of Platelet-Rich Plasma (PRP) on Sinonasal Polyposis

Protocol summary

Study aim

This study was to determine the effect of Platelet-Rich Plasma (PRP) on improvement of endoscopic sinus surgery outcome patients with chronic rhinosinusitis with Sinonasal Polyposis.

Design

Two arm parallel group randomized clinical trial with triple blinded postoperative care and outcome assessment

Settings and conduct

One side of the nose randomly consider as a control by the researcher and the other side intraoperatively PRP spray into all polyposis areas such as maxillary sinus, spheroidal sinus, ethmoidal sinus and frontal recess. There was no medication therapy before the surgery for none of the patients and for post operation medications cephalixin will describe for 7 days. sinus CT scan, SNOT-22 questionnaire, Meltzer scores and Lund-Mackay scores completed for all patients before the surgery and will compare with 6 month after the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age older than 18 years old; patients with bilateral chronic rhinosinusitis with polyposis; refractory to medical management; candidate for functional endoscopic sinus surgery (FESS). Exclusion criteria: patients with unilateral disease; patients with platelet function disorders; thrombocytopenia; history of other co-morbidities; patients with aspirin allergy.

Intervention groups

10 milliliters of patient's blood were collected. Nine milliliters of blood together + 1 milliliters of acid/citrate/dextrose used as an anticoagulant. Centrifuged two times at 1500 & 2000 rpm for 10 minutes. PRP prepared as spray and gel at the end of endoscopic sinus surgery was sprayed into all polyposis areas in one side of the nose and maxillary sinus, sphenoid sinuses, ethmoidal sinus and frontal recess. On the other side of the nose, which is selected as a control, no substance will be injected.

Main outcome variables

Quality of life scores; sinus CT scan findings; endoscopic findings

General information

Reason for update

Acronym

PRP

IRCT registration information

IRCT registration number: **IRCT20181225042111N1**

Registration date: **2019-04-10, 1398/01/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-10, 1398/01/21**

Update count: **0**

Registration date

2019-04-10, 1398/01/21

Registrant information

Name

Saleh Mohebbi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2658

Email address

mohebbi.sa@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Platelet-Rich Plasma (PRP) on Sinonasal Polyposis

Public title

Comparison of the effects of Platelet-Rich Plasma (PRP) on Sinonasal Polyposis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years old Refractory to medical management Candidate for functional endoscopic sinus surgery (FESS) Patients' Informed consent

Exclusion criteria:

Patients with unilateral disease Patients with platelet function disorders Thrombocytopenia History of other co-morbidities Patients with aspirin allergy

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

The random number table was used to determine which of the right or left sides of the nose the PRP was used. So that, if the selected number of table was paired, PRP was used for the right side of the nose, otherwise it was used for the left side of the nose.

Randomization (investigator's opinion)

Randomized

Randomization description

Before starting the study, 4 part blocks consisting A and B were generated randomly. Patients nostril (right or left) were assigned to blocks consecutively. One side was randomly considered as a control and the other side at the end of each surgery intraoperatively PRP was sprayed so two randomising groups were determined.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is triple blind. The patient, evaluators and analyzer had no information about the injection side.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar Khan Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2018-10-23, 1397/08/01

Ethics committee reference number

IR.IUMS.FMD.REC.1397.245

Health conditions studied**1****Description of health condition studied**

Nasal polyp, unspecified

ICD-10 code

J33

ICD-10 code description

Nasal polyp, unspecified

Primary outcomes**1****Description**

Nasal and sinonasal polyposis

Timepoint

Before injection, 6 month after intervention

Method of measurement

The SNOT-22 questionnaire was used to show the quality of life related symptoms in before and after intervention.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: under treatment with platelet-rich plasma (PRP) spray intraoperatively in endoscopic sinus surgery

Category

Treatment - Drugs

2

Description

Control group: in nostril is chosen as a control no material will be sprayed or injected intraoperatively in endoscopic sinus surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasoul Hospital

Full name of responsible person

Dr Saleh Mohebbi

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar khan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2658

Fax

+98 21 6652 5329

Email

mohebbi54@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Malakooti

Street address

Hemmat Expressway, Iran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2504

Fax

+98 21 6652 5329

Email

admins@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Farideh Hosseinzadeh

Position

Resident of Otolaryngology- Head and Neck Surgery

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar khan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2658

Email

Hosseinzadeh.farideh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Saleh Mohebbi

Position

Assistant Professor of Otolaryngology- Head and Neck Surgery

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Hazrat Rasoul Akram Hospital, Niayesh St., Sattar khan Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2658

Email

mohebbi54@gmail.com

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2658

Email

mohebbidr@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Alireza Mohebbi

PositionAssistant Professor of Otolaryngology- Head and Neck
Surgery**Latest degree**

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street addressHazrat Rasoul Akram Hospital, Niayesh St., Sattar
khan Ave., Tehran**City**

Tehran

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**

Not applicable

Informed Consent FormUndecided - 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