

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Malakooti

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

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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**

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

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**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

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

Iran University of Medical Sciences

**Full name of responsible person**

Alireza Mohebbi

**Position**Assistant Professor of Otolaryngology- Head and Neck  
Surgery**Latest degree**

Specialist

**Other areas of specialty/work**

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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**

Not applicable

**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