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 cephalexin 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

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Iran (Islamic Republic of)

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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 spraye 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
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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
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1

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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

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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