

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

**Investigating the effect of using autologous platelet factor in accelerating mastoidectomy repair with removal of the posterior wall and comparing it with the control group.**

### Protocol summary

#### Study aim

The use of autologous platelet factor in accelerating CWD mastoidectomy recovery and comparison with the control group

#### Design

The clinical trial has a control group with parallel groups, a single-blind, randomized phase 2-3 using sealed envelope, single-center and includes 50 patients.

#### Settings and conduct

This single-blind randomized controlled clinical trial (the participants in the study are blinded) in the ENT department of Imam Reza Hospital, Mashhad, on 50 patients for mastoidectomy. Eligible patients are divided into control and intervention groups after obtaining consent. In the control group, only Gelfoam will be used, but in the intervention group, in addition to Gelfoam, 4 to 8 cc of throat fibrin enriched with platelets are used, which is located in the area inside the middle ear below and above.

#### Participants/Inclusion and exclusion criteria

Patient satisfaction and performing mastoidectomy operation by removing the posterior wall and not suffering from anemia and no complications during the operation

#### Intervention groups

In the control group, only 4 to 8 cc of Gelfoam will be used, but in the intervention group, in addition to Gelfoam, 4 to 8 cc of throat fibrin enriched with platelets (Blood Transfusion Organization of Iran, Mashhad, Iran) would be used, which is placed inside the middle ear.

#### Main outcome variables

The duration of epithelialization of the eardrum

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20211010052721N3**

Registration date: **2022-10-22, 1401/07/30**

Registration timing: **retrospective**

Last update: **2022-10-22, 1401/07/30**

Update count: **0**

#### Registration date

2022-10-22, 1401/07/30

#### Registrant information

##### Name

Navid nourizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 2081

##### Email address

nourizadehn@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-11-21, 1399/09/01

#### Expected recruitment end date

2021-08-23, 1400/06/01

#### Actual recruitment start date

2021-03-21, 1400/01/01

#### Actual recruitment end date

2022-01-20, 1400/10/30

#### Trial completion date

2022-04-19, 1401/01/30

#### Scientific title

Investigating the effect of using autologous platelet factor in accelerating mastoidectomy repair with removal

of the posterior wall and comparing it with the control group.

**Public title**  
Investigating the effect of autologous platelet factor in ear repair

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patient satisfaction Performing mastoidectomy by removing the posterior wall  
**Exclusion criteria:**  
Having anemia Complications during surgery such as facial paralysis Breastfeeding Pregnancy

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **50**  
Actual sample size reached: **50**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization with "www.randomization.com" website will be done. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The study subjects will be unaware of the intervention and control groups. In this study because placebo will be used in parallel with the drug, the participants will not know whether the drug or the placebo is being used.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9117699199  
**Approval date**  
2020-11-17, 1399/08/27  
**Ethics committee reference number**  
IR.MUMS.MEDICAL.REC.1399.605

## Health conditions studied

### 1

#### Description of health condition studied

Mastoidectomy

#### ICD-10 code

H95.1

#### ICD-10 code description

Other disorders of ear and mastoid process following mastoidectomy

## Primary outcomes

### 1

#### Description

The duration of epithelialization of the eardrum

#### Timepoint

At the beginning of the study (before the start of the intervention) and 14, 30 and 90 days after the use of autologous platelet factor

#### Method of measurement

Otoscopy with a microscope

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group of patients, in addition to Gelfoam, from 4 to 8 cc of throat fibrin enriched with platelets (Iranian Blood Transfusion Organization, Mashhad, Iran) will be used which is placed in the middle ear area above and below.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group of patients, only 4 to 8 cc of Gelfoam (Blood Transfusion Organization of Iran, Mashhad, Iran) will be used which is placed in the area of the middle ear below and above.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Navid Noorizadeh

**Street address**

Imam Reza (AS) Hospital, Imam Reza (AS) Square, Ibn Sina St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1394491388

**Phone**

+98 51 3845 1521

**Email**

nourizadeh@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayormbarhan

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Navid Nourizadeh

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ear, Nose, and Throat

**Street address**

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**Phone**

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**Email**

Nourizadehn@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Navid Nourizadeh

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Associate professor

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## Person responsible for updating data

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**Name of organization / entity**

Mashhad University of Medical Sciences  
**Full name of responsible person**  
Navid Nourizadeh  
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**Postal code**  
1394491388  
**Phone**  
009838451521

**Email**  
Nourizadehn@mums.ac.ir

## 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

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available