

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the effectiveness of Platelet-Rich Fibrin on the survival of Diced cartilage in rhinoplasty candidate patients

Protocol summary

Study aim

Evaluating the effectiveness of platelet-rich fibrin injection in diced cartilage survival rate in rhinoplasty

Design

A clinical trial with a control group, with crossover groups, one-sided blind, randomized, on 40 patients, randomization was computerized with RAND function of Excel.

Settings and conduct

This study is a randomized controlled clinical trial one blinded. Patients are randomly placed in one of the coded groups and will undergo rhinoplasty, and the patient does not know about the procedure. Patients who are candidates for rhinoplasty and do not have a history of hematological diseases will be included in the study after obtaining written consent, and their information, including age, gender, underlying diseases, and medications will be extracted from the file. Patients will be placed in one of the groups after randomization. After treatment, patients are evaluated by ultrasound (cartilage survival rate), Utrecht questionnaire (patient satisfaction), and nose examination by a skilled surgeon (evaluation of cartilage irregularities in four injection sites).

Participants/Inclusion and exclusion criteria

Rhinoplasty candidate Absence of hematologic diseases

Intervention groups

Control group: patients who are operated with diced cartilage during rhinoplasty. PRF group: patients who are operated with diced cartilage and PRF during rhinoplasty.

Main outcome variables

The survival rate of remaining cartilage in volume scale (ultrasound) Assessment of injection site irregularities in four points (nasal examination by a skilled surgeon) Patient satisfaction (Utrecht questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221011056150N1**

Registration date: **2023-01-07, 1401/10/17**

Registration timing: **retrospective**

Last update: **2023-01-07, 1401/10/17**

Update count: **0**

Registration date

2023-01-07, 1401/10/17

Registrant information

Name

Elham Zahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4494 3270

Email address

zahabie71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

2020-05-21, 1399/03/01

Actual recruitment end date

2021-09-23, 1400/07/01

Trial completion date

2021-09-23, 1400/07/01

Scientific title

Evaluating the effectiveness of Platelet-Rich Fibrin on the survival of Diced cartilage in rhinoplasty candidate patients

Public title

Evaluating the effect of Platelet-Rich Fibrin on the survival of Diced cartilage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Rhinoplasty candidate patients

Exclusion criteria:

Hematologic diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria are placed in one of the two groups of rhinoplasty without PRF (group A) or rhinoplasty with PRF (group B). Randomization is done based on the (RAND) function of Excel software and based on this, a table of random numbers is prepared, and patients are placed in groups A or B according to the rows of this table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Considering that the intervention is of surgical type, only the patients have been kept blind and the surgeon and clinical assessor and those responsible for data collection know about the grouping of the patients.

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

Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.IUMS.FMD.REC.1399.150

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sonographic result

Timepoint

One year after surgery

Method of measurement

Ultrasound (cartilage viability)

2

Description

Clinical examination of skilled surgeon

Timepoint

One year after surgery

Method of measurement

Grading by the surgeon - Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes 20 rhinoplasty candidates who meet the inclusion criteria, whose order and type of intervention is randomly based on the (RND) function of Excel software. These patients receive diced cartilage mixed with platelet-rich fibrin during rhinoplasty. One year after the surgery, the cartilage is evaluated by ultrasound and evaluations by a skilled surgeon.

Category

Treatment - Surgery

2

Description

Control group: includes 20 rhinoplasty candidates who meet the inclusion criteria, whose order and type of

intervention is randomly based on the (RND) function of Excel software. These patients receive diced cartilage without platelet-rich fibrin during rhinoplasty. One year after the surgery, the cartilage is evaluated by ultrasound and evaluations by a skilled surgeon.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Alireza Mohebi

Street address

Niyayesh Ave. Satarkhan Blvd.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2417

Fax

Email

mohebbi@ariums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Keyvani

Street address

Hemat High way, next Milad tower

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2417

Email

keyvani.h@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

Elham Zahabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

No. 22/9 , North bahar St , west ferdous Blvd

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 4494 3270

Fax

Email

zahabie71@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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Resident

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

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