

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of topical injection of platelet-rich fibrin on the thickness of nasal skin in people undergoing rhinoplasty by ultrasonography

Protocol summary

Study aim

Determining the relationship between platelet-rich fibrin injection and the quality of nasal skin thickness using nasal skin ultrasound

Design

A clinical trial without a control group, non-randomized, with a sample size of 10 people (comparison before and after the intervention)

Settings and conduct

Masih Deneshvari hospital is the otolaryngology clinic. 30 cc of venous blood sample is taken from the person's blood and collected in 15 ml plastic coated tubes without using anticoagulants. Then the tubes are immediately placed opposite each other inside the centrifuge and centrifuged at 800 revolutions per minute for four minutes. The yellow-orange upper liquid obtained is ready for injection. The above actions are performed with all aseptic precautions. The participants undergo ultrasound examination once before the injection and three times after the injection in order to compare the thickness of the nasal skin. And the skin thickness of people before and after injection is compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: who want rhinoplasty or a history of rhinoplasty surgery Exclusion criteria: history cancer of sinus and nose, diabetes , platelet dysfunction

Intervention groups

The intervention group includes people who had a history of rhinoplasty surgery or are planning to undergo rhinoplasty surgery, who are injected with fibrin solution rich in platelets. The participants undergo ultrasound examination once before the injection and three times after the injection in order to compare the thickness of the nasal skin. And the skin thickness of people before and after injection is compared

Main outcome variables

Examination of the quality of the nasal skin and the

thickness of the nasal skin; The amount of blood supply in the skin of the nose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043360N1**

Registration date: **2023-02-27, 1401/12/08**

Registration timing: **retrospective**

Last update: **2023-02-27, 1401/12/08**

Update count: **0**

Registration date

2023-02-27, 1401/12/08

Registrant information

Name

Jahangir Ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2610 5242

Email address

jghorbani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of topical injection of platelet-rich fibrin on the thickness of nasal skin in people undergoing rhinoplasty by ultrasonography

Public title
Investigation of the effect of platelet-rich fibrin on skin thickness

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
who want rhinoplasty or have a history of rhinoplasty
Exclusion criteria:
History of nasal and sinus cancer diabetes disease of Impairment of wound tissue repair Blood platelet disorders and the use of anticoagulants History of platelet-rich fibrin injection

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
The effectiveness of platelet-rich fibrin on improving the thickness of nasal skin has not been studied in Iran

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran Darabad Masih daneshvari Hospital

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2021-12-02, 1400/09/11

Ethics committee reference number

IR.SBMU.NRITLD.REC.1400.078

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of injection of platelet-rich fibrin on the thickness of the nasal skin

Timepoint

Examination of skin thickness with ultrasound before injection and one week, two weeks and three weeks after

Method of measurement

Thickness in the dermis, epidermis and subcutaneous tissue is measured and measured. Equipment used for Medison sonoac 8000se ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

After a complete explanation about the study and obtaining their consent, first 30 cc of venous blood samples are taken from the person's blood and collected in 15 ml plastic coated tubes without the use of anticoagulants. Then the tubes are immediately placed opposite each other inside the centrifuge and centrifuged at 800 revolutions per minute for four minutes. The yellow-orange upper liquid obtained is ready for injection. The above actions are performed with all aseptic precautions. The participants undergo ultrasound examination four times in order to compare the thickness of the nasal skin. The first stage is before the injection and the next three stages are one, two and three weeks after the injection. Ultrasound will be performed by a high-frequency linear probe by the center's expert radiologists who are familiar with ultrasound. During the ultrasound process, the thickness of the skin along with changes in echogenicity and the presence of vascularity will be checked and compared with the thickness before the injection. The thickness in the dermis, epidermis and subcutaneous tissue is checked and measured. The

equipment used for ultrasound is Medison sonoac 8000se at a frequency of 5-9 MHz.

Category

Treatment - Drugs

empty

Country of origin

Type of organization providing the funding

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih daneshvari hospital

Full name of responsible person

Jahangir Ghorbani

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Tehran. Darabad St. Masih daneshvari hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Jahangir Ghorbani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

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Position

Associate professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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