

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of thickness and number of follicular units with or without Platelet- rich plasma in hair transplantation procedure

Protocol summary

2013-09-08, 1392/06/17

Summary

This randomized controlled trial is performed among a group of 88 patients attending to clinics of Skin and Stem cell Research Center of Tehran scheduled for hair transplantation surgery. Inclusion Criteria: Subjects are recruited from a group of patients attending to clinics of Skin and Stem cell Research Center of Tehran scheduled for hair transplantation surgery. Exclusion Criteria: Patients who will not return for follow up visits or are not willing to participate will be excluded. The protocol of the trial is described in details and a written consent would be obtained from all subjects. Patients are randomly assigned into two groups. The first group will receive routine hair transplantation surgery by follicular unit transplantation (FUT) method and are considered as the control group. The second group will receive both Platelet- rich plasma (PRP) and FUT methods. A sample of 20 cc of whole blood would also be obtained from participants of the second group. In this study the major independent variable is treatment groups and the number and thickness of successful transplanted follicular units would be measured as the dependent variable. Patients in both groups will receive standard medical therapy. After transplantation daily finasteride and topical minoxidil initiating at 2 weeks postoperatively will be prescribed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904021159N5**

Registration date: **2013-09-08, 1392/06/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of thickness and number of follicular units with or without Platelet- rich plasma in hair transplantation procedure

Public title

Comparison of follicular units with or without Platelet-rich plasma in hair transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Subjects are recruited from a group of patients attending to clinics of Skin and Stem cell Research Center of Tehran scheduled for hair transplantation surgery. Exclusion Criteria: Patients who will not return for follow up visits or are not willing to participate will be excluded.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-06-11, 1391/03/22

Ethics committee reference number

56317

Health conditions studied

1

Description of health condition studied

Alopecia

ICD-10 code

L65.9

ICD-10 code description

Nonscarring hair loss

Primary outcomes

1

Description

Number of follicular units

Timepoint

Before transplantation and 4, 8, 12 months after transplantation

Method of measurement

Trichoscan

2

Description

Thickness of follicular units

Timepoint

Before transplantation and 4, 8, 12 months after transplantation

Method of measurement

Trichoscan

Secondary outcomes

empty

Intervention groups

1

Description

Hair transplantation by follicular unit transplantation (FUT) method: One time, a thin donor with 1-2 cm width is received from back of head and then is divided to follicular units by stereo microscope and transplanted in recipient site.

Category

Treatment - Surgery

2

Description

Hair transplantation by Platelet- rich plasma (RPR) plus follicular unit transplantation (FUT) method: One time, a 20 cc blood sample is obtained from each participant, and will be centrifuged for 5 minutes at 1400 rpm to separate blood cells from platelets by Tubex kit (from Seoul, South Korea) in Selex centrifuge. A part of obtained suspension will be kept for maintaining the grafts while the other part is sprayed during the hair transplantation procedure.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of
Tehran University of Medical Sciences

Full name of responsible person

Azadeh Zolfaghari

Street address

Tehran University of Medical Sciences, Enghelab
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Isfahan University of Medical Sciences, Sedigheh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Vice chancellor for research, Tehran University of
Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Diseases and Leishmaniasis Research Center,
Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Azadeh Zolfaghari

Position

MSc

Other areas of specialty/work

Street address

Skin Diseases and Leishmaniasis Research Center,

Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences, Tehran, Iran

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Associate professor

Other areas of specialty/work

Street address

Skin and Stem Cell Research Center, third floor, no 4,
Maryam impasse, Kamranieh st, Tehran

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Tehran

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Fax

Email

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty