

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

efficacy of platelet rich plasma versus 5% topical minoxidil for the treatment of androgenetic alopecia

Protocol summary

Study aim

To determine the efficacy of Platelet Rich Plasma (PRP) versus 5% topical minoxidil for the treatment of androgenetic alopecia

Design

randomized control trial (RCT) parallel group, single blinded study 35 patients will be assigned in each group, randomization will be done by lottery method, a single center study

Settings and conduct

PNS Shifa Karachi after approval from ethical committee, blinding is done for photographic examination, as mentioned earlier

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 18 to 60 years. Patient Hamilton-Norwood grade ≥ 2 and ≤ 5 or Ludwig scale grade 1-2. Platelets count more than 150,000 / μ l. Duration of androgenetic alopecia > 6 months. Patient has not taken any kind of medical treatment for hair loss or has not used treatment for more than 6 months duration.
Exclusion criteria Patients with alopecia other than AGA, such as telogen effluvium, alopecia areata, acquired cicatricial alopecia, or anagen effluvium. The patient on warfarin or heparin. The infective disease of the scalp. Patient who has taken any treatment for androgenetic alopecia. History of thyroid disorder. Patients with hypersensitivity to minoxidil in past. Any infective skin disease. Pregnancy / lactation. Patient taking aspirin. Unrealistic expectation.

Intervention groups

30 ml of venous blood will be drawn into a tube containing citrate phosphate dextrose, it will be subjected to centrifugation by two spins to produce PRP. Calcium gluconate to PRP ratio used will be 1:9 this will be injected intradermally, each session 1 month apart. Participants of group B will be advised to apply topical 5% minoxidil 1 ml over dry scalp 12 hourly.

Main outcome variables

hair pull test, investigator 7 point score, patient

satisfaction score, patient standardized hair growth questionnaire, photographic evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052139N1**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Ghazal Afzal

Name of organization / entity

PNS SHIFA KARACHI Sindh

Country

Pakistan

Phone

+92 21 48506540

Email address

ghazalafzal@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-04-30, 1401/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
efficacy of platelet rich plasma versus 5% topical minoxidil for the treatment of androgenetic alopecia

Public title
efficacy of PRP versus topical 5% minoxidil spray in treatment of pattern baldness

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years patient has not taken any kind of medical treatment for hair loss or has not used treatment for more than 6 months duration of AGA >6 months Patient Hamilton-Norwood grade ≥ 2 and ≤ 5 or Ludwig scale grade 1-2. Platelets count more than 150,000 / μ l
Exclusion criteria:
 Patients with alopecia other than AGA, such as telogen effluvium, alopecia areata, acquired cicatricial alopecia, or anagen effluvium. The patient on warfarin or heparin the infective disease of scalp patients who has taken any treatment for AGA history of thyroid disorder patient with hypersensitivity to minoxidil in past any infective skin disease pregnancy/lactation patient taking aspirin unrealistic expectation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **35**
individuals will be selected by applying inclusion and exclusion criteria

Randomization (investigator's opinion)
Randomized

Randomization description
randomized by lottery method (each patient presenting to dermatology out patient department for androgenetic alopecia will be assigned a number and will be selected randomly so each patient has same probability to be included in the study)

Blinding (investigator's opinion)
Single blinded

Blinding description
response to treatment will be assessed as follows Patient hair should be dry and clean. He will be advised to maintain the same hair style and hair colour on each visit. Appropriate lightening will be used; multiple images will be shot at vertex and mid pattern. For vertex view patient will be asked to look at the ceiling. For mid

pattern patient will be instructed to place hand flat on table with fingers of both hands interlocked, and now place his/her face on hand. Results will be interpreted by investigator 7 point score [14]. - 3 = greatly decreased -2 = moderately decreased -1 = slightly decreased 0 = no change 1 = slightly increased 2 = moderately increased 3 = greatly increase photograph will be taken at 0, 3, and 6 months one dermatologist will be blinded to the treatment group of the patient

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hospital Ethical and Research Committee PNS shifa karachi

Street address

Main Korangi Rd, near Kala Pul. Clifton, Karachi, Karachi City, Sindh PNS Shifa Hospital, address

City

karachi

Postal code

07011

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

ERC/2021/DERMATOLOGY/57

Health conditions studied

1

Description of health condition studied

Androgenetic Alopecia

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes

1

Description

photographic evaluation

Timepoint

at 0, 3, and 6 months

Method of measurement

photographic evaluation, patient satisfaction score, investigator 7 point score, Patient standardized hair growth questionnaire

2

Description

patient satisfaction score

Timepoint

6 month

Method of measurement

this is measured by using standarize patient satisfaction score,0: no improvement 1: 1%-25% improvement 2: 25%-50% improvement 3: 50%-75% improvement 4: 76%-100% improvement

3

Description

investigator 7 point score,

Timepoint

0 and 6 month, - 3 = greatly decreased -2 = moderately decreased-1 = slightly decreased0 = no change 1 = slightly increased 2 = moderately increased3 = greatly increased

Method of measurement

using serial photograph taken at 0,3 and 6 months,improvement in hair density will be noted

4

Description

Patient standardized hair growth questionnaire

Timepoint

6 month

Method of measurement

with answer of questions regarding hair loss

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: After all aseptic measures 30 ml of venous blood will be drawn into a tube containing citrate phosphate dextrose (prevent platelet activation and degranulation), blood then subjected to two spins, a soft spin at 2500 rpm for 10 minutes and a hard spin at 3500 rpm for 15 minutes, the soft spin will separate blood in 3 layers lowermost layer is of RBC (Red blood cells), the uppermost layer is PPP (platelet-poor plasma) and the middle layer is PRP (platelet-rich plasma). In another tube PPP, PRP and a few RBC without anticoagulant will undergo hard spin. In this way, PRP will be settled at the bottom and PPP at the uppermost layer. PPP will be discarded and the remaining PRP will be used for the procedure. For procedure, this PRP will be collected in a sterile insulin syringe containing calcium gluconate which acts as an activator for platelets. Calcium gluconate to PRP ratio used will be 1:9. Now, this activated and highly concentrated PRP will be injected intradermally, in a dose of 0.1 -0.2 ml per injection 1 cm apart in interfollicular regions. A total of 6 sessions will

be done, each session 1 month apart

Category

Treatment - Drugs

2

Description

Intervention group2: . Participants of group B will be advised to apply topical 5% minoxidil 1 ml over dry scalp 12 hourly. Participants of both groups will be assessed on 0, 3, and 6 months. The serial photographs will be taken at each assessment. The Final outcome i.e. efficacy (as mention above) will be measured after 6 months of starting treatment. Confounding variables and bias will be controlled by strictly following inclusion and exclusion criteria.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

PNS shifa Hospital karachi sindh pakistan

Full name of responsible person

Ghazal Afzal

Street address

Main Korangi Rd, near Kala Pul. Clifton, Karachi, Karachi City, Sindh PNS Shifa Hospital, address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

PNS shifa karachi

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?

No

Title of funding source

PNS shifa karachi

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

PNS shifa karachi

Full name of responsible person

Ghazal afzal

Position

post graduate trainee

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

PNS shifa karachi

Full name of responsible person

Ghazal afzal

Position

post graduate trainee

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

post graduate trainee

Latest degree

Medical doctor

Other areas of specialty/work

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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

Not applicable

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