Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

efficacy of platelet rich plasma versus5% 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 assign in each group,radomization 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 than150, 000 /µl.Duration of androgebetic 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

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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 versus5% topical minoxidil for the treatment of androgenetic alopecia

Public title

efficacy of PRP versus topical 5% minoxidil spray in treatmemt 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 duration of AGA >6months Patient Hamilton-Norwood grade ≥2 and ≤ 5 or Ludwig scale grade 1-2. Platelets count more than150, 000 /µl

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 patoents 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 takinh 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
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Sponsors / Funding sources

1

Sponsor
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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
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Position
post graduate trainee
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Medical doctor
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Other areas of specialty/work
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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
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