Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Biofiller Vs Platelet rich plasma mesotherapy in the treatment of Peri-orbital hyperpigmentation in patients presenting to outpatient department of dermatology in a tertiary care hospital-An RCT

Protocol summary

Study aim
To establish efficacy of Biofiller Vs platelet rich plasma mesotherapy in treatment of peri-orbital hyper pigmentation.

Design
A clinical trial with two parallel intervention groups, double-blind, on 42 patients, phase 3; randomized using sealed envelopes.

Settings and conduct
Dermatology opd of our tertiary care hospital (Pak Emirates Military Hospital, Rawalpindi, Pakistan). Photographs will be taken at the start of treatment and then 01 months after the last treatment. A validated photo-numeric scale for infraorbital dark circles proposed by M.M. O'Mahony et al, will be used in our study as objective measurement of periorbital dark circles intensity before and after treatment. Moreover, medical observer will perform clinical assessments using the following grading scale: 0, < 25% improvement (poor); 1, 26–50% improvement (fair); 2, 51–75% improvement (good); 3, 75–90% improvement (excellent); and 4, 91–100% improvement (complete).

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with Fitzpatrick skin types 1-4; Patients with peri-orbital hyperpigmentation willing to participate in our study; aged 18-65 years. Exclusion Criteria: Patients of Fitzpatrick skin type 5 or 6; Using or have used other treatments for dark circles; Pregnant women; Patients on anti-platelet / anticoagulants /fibrinolytics; Patients on immunosuppressant medications; Patients having Hep B or C or HIV.

Intervention groups
Intervention group 1 will be patients treated by bio fillers for peri-orbital hyperpigmentation; Intervention group 2 will be patients treated by PRP mesotherapy for peri-orbital hyperpigmentation.

Main outcome variables
The validated photo-numeric scale proposed by M.M. O'Mahony et al

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230816059168N1**
Registration date: **2023-08-28, 1402/06/06**
Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**
Update count: **0**

Registration date
2023-08-28, 1402/06/06

Registrant information

Name
Sakina Sadiq Malik

Name of organization / entity
National University of Medical Sciences

Country
Pakistan

Phone
+92 321 5108737

Email address
dazzlingdocsak2078@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-01, 1402/06/10

Expected recruitment end date
2023-12-31, 1402/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Biofiller Vs Platelet rich plasma mesotherapy in the treatment of Peri-orbital hyperpigmentation in patients presenting to outpatient department of dermatology in a tertiary care hospital-An RCT

Public title
Bio filler Vs Platelet rich plasma mesotherapy in the treatment of Peri-orbital hyperpigmentation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with peri-orbital hyperpigmentation willing to participate in our study. Patients with peri-orbital hyperpigmentation, aged 18-65 years. Patients of Fitzpatrick skin type 1-4.
Exclusion criteria:
Patients having Hep B or C or HIV (as PRP and bio fillers are blood products and dealing with infected people can be hazardous for treating staff). Patients on immunosuppressant medications due to other diseases Pregnant women. Patients on anti-platelet or anticoagulants or fibrinolytics Patients using or have used other treatments for dark circles Patients of Fitzpatrick skin type 5 or 6
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple, Non-probability randomized sampling in patients divided into two random groups by use of lottery method in individuals by giving the patients sealed envelopes of 2 types to choose one blindly from one of them.And afterwards divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients fulfilling the inclusion criteria and excluding the exclusion criteria will be randomly divided into two groups by lottery method. Half of them will be treated by bio fillers and another half by PRP mesotherapy. They will not be knowing, which treatment they are undergoing. After 01 month of completion of treatment another dermatologist will blindly assess the results. He/she will not be knowing which treatment the patient underwent, as both are injected by injection and cannulas peri-orbitally.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical commitee Pak Emirates Military Hospital
Street address
Saddar,Rawalpindi
City
Rawalpindi
Postal code
44000
Approval date
2023-08-10, 1402/05/19
Ethics committee reference number
A/28/EC/576/23

Health conditions studied

1

Description of health condition studied
Peri orbital hyperpigmentation
ICD-10 code
L81.4
ICD-10 code description
Other melanin hyperpigmentation

Primary outcomes

1

Description
Photographs will be taken at the start of treatment and then 01 months after the last treatment. A validated photo-numeric scale for infraorbital dark circles proposed by M.M. O'Mahony et al, will be used in our study as objective measurement of periorbital dark circles intensity before and after treatment.
Timepoint
01 month after the last treatment
Method of measurement
Photo-numeric scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Topical eutectic mixture of local anesthetic cream will be applied over the patient's face around eyes for 45 min. Ten milliliters of patient's blood will be drawn and mixed with 1 mL anticoagulant acid citrate dextrose. It will be rotated at 3500 rotations per minute (RPM) for 15 min and then centrifuged again at 1500 RPM for 5 min. The upper part that is platelet-poor plasma (PPP) will be withdrawn in a 5 mL syringe, approximately 4.5 cc. PPP will be incubated in hot water at 100°C for 5 min and then cooled in a refrigerator for 5 min. The viscous gel, approximately 3 to 4 ml in volume, will be ready for use. After cleaning of the topical anesthetic cream, PPP gel filler will be injected below the dermis just above the bone with 27G cannula in a linear threading technique. The sites were gently massaged to allow uniform distribution of the injected plasma gel to maintain the contour of the surrounding tissues. Patient will be advised to avoid NSAIDS for 5-7 days' post procedure. This procedure will be repeated 2 times in a monthly interval.

Category

Treatment - Other

2

Description

Intervention group 2: Topical eutectic mixture of local anesthetic cream will be applied over the patient's face around eyes for 45 min. Ten milliliters of patient's blood will be drawn and mixed with 1 mL anticoagulant acid citrate dextrose. It will be rotated at 3500 rotations per minute (RPM) for 15 min and then centrifuged again at 1500 RPM for 5 min. The lower part that is PRP was withdrawn in 3 insulin (1 mL) syringes, approximately 2.5 ml. It will be injected by meso- therapy around 2 ml around each eye avoiding blood vessels and, hence bruising. Patient will be advised to avoid NSAIDS for 5-7 days' post procedure. This procedure will be repeated 2 times in a monthly interval.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Pak Emirates Military Hospital

Full name of responsible person
Dr.Sakina Sadiq Malik

Street address
Saddar,Rawalpindi

City
Rawalpindi

Postal code
44000

Phone
+92 321 5108737

Email
dazzlingdocsak2078@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Self

Full name of responsible person
Dr.Sakina Sadqi Malik

Street address
Saddar,Rawalpindi

City
Rawalpindi

Postal code
44000

Phone
+92 321 5108737

Email
dazzlingdocsak2078@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Self

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
AM college Rwp

Full name of responsible person
Dr.Sakina Sadiq Malik

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Saddar,Rawalpindi

City
Rawalpindi

Province
Punjab

Postal code
44000
Phone
+92 321 5108737
Email
dazzlingdocsak2078@hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
AM college Rwp
Full name of responsible person
Dr.Sakina Sadiq Malik
Position
Assistant professor of dermatology
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Saddar,Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code
44000
Phone
+92 321 5108737
Email
dazzlingdocsak2078@hotmail.com

Person responsible for updating data

Contact
Name of organization / entity
National university of medical sciences
Full name of responsible person
Sakina Sadiq Malik
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Saddar,Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code
44000
Phone
+92 321 5108737
Email
dazzlingdocsak2078@hotmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Biofiller Vs Platelet rich plasma mesotherapy in the treatment of Peri-orbital hyperpigmentation
When the data will become available and for how long
after the study will be published
To whom data/document is available
open access
Under which criteria data/document could be used
will be available on research gate
From where data/document is obtainable
Research gate after publication
What processes are involved for a request to access data/document
E-mail
Comments