

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 hyperpigmentation.

##### 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 committee 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

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## 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  
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## 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**  
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**City**  
Rawalpindi  
**Province**  
Punjab  
**Postal code**  
44000  
**Phone**  
+92 321 5108737  
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## 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