

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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44000

Phone

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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

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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

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

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Specialist
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Person responsible for updating data

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Other areas of specialty/work

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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