

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparision of the effectiveness of platelet-rich plasma (PRP) and tranexamic acid + vitamin C mesotherapy in the treatment of periorbital hyperpigmentation (POH)

Protocol summary

Study aim

Comparision of the effectiveness of PRP and tranexamic acid + vitamin C mesotherapy in the treatment of periorbital hyperpigmentation

Design

Randomized clinical trial with control group and parallel group, double-blind, with 20 participants, for randomization we used the random numbers table.

Settings and conduct

This is a double-blind randomized controled trial, 20 male or female participants with minimum age of 18 with diagnosed periorbital hyperpigmentation attending dermatology clinic in Afzalipour hospital in kerman enroll the study. intervention and control groups will be selected accidentally, intervention group will recieve mesotherapy with tranexamic acid & vitamin C, control group will recieve PRP injection. participants and evaluator of the treatment response are blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : - Diagnosis of non-structural POH by dermatologist in Afzalipour hospital dermatology clinic - Filling the written letter of satisfaction to participate in the project - Minimum age of 18 when filling the letter of satisfaction - Male or non-pregnant, non-breast feeding female gender Exclusion criteria : - Pregnancy and lactation - Age under 18 and above 65 years old - Smoking - Previous or current bleeding disorders - Using anti coagulant medications - Presence of any active lesion in the treatment area

Intervention groups

Intervention group A will recieve mesotherapy with tranexamic acid & vitamin C in 3 sessions with 3 week intervals, and in control group B PRP injection will be done in 3 sessions with 3 week intervals.

Main outcome variables

Degree of pigmentation, improvement scale, patient

satisfaction scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200623047891N2**

Registration date: **2022-08-21, 1401/05/30**

Registration timing: **retrospective**

Last update: **2022-08-21, 1401/05/30**

Update count: **0**

Registration date

2022-08-21, 1401/05/30

Registrant information

Name

Najme sadat Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3226 3162

Email address

njs.hashemi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effectiveness of platelet-rich plasma (PRP) and tranexamic acid + vitamne C mesotherapy in the treatment of periorbital hyperpigmentation (POH)

Public title

Assessing effectiveness of PRP and tranexamic acid + vitamne C mesotherapy in the treatment of periorbital dark circle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of non-structural POH by dermatologist in Afzalipour hospital dermatology clinic Filling the written letter of satisfaction to participate in the project Minimum age of 18 when filling the letter of satisfaction Male or non-pregnant, non-breast feeding female gender

Exclusion criteria:

Smoking Previous or current bleeding disorders Using anti coagulant medications Presence of any active lesion in the treatment area

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

20 participants will participate in this trial. because there is right and left side fore the face of each participant, there is 40 areas for treatment. we allocate the letter R to the right side of each participant and the letter L to the left side. Then we organize the letters R & L from number 1 to 40 (i.e RLRLRL...RL). One row and one column will be randomly chosen from the table of random numbers; the intersection between this row and column will be the starting point for sampling. A finger will be put on the starting point and will be moved downwards through the table. Because there should be 20 areas in the intervention group A (tranexamic acid & vitamin C) and 20 areas in the control group B (PRP) , the two digits at the right side of each number in the table will be considered. The moving of finger will be repeated until 20 areas of the intervention group A will be chosen. Duplicate numbers and numbers larger than 40 will not be considered. In this way, it will be found out that which 20 numbers among all of the 40 numbers given to the whole areas will be allocated to the intervention group A (e.g. numbers 3, 4, 9, 11, 13, 14, ...). The remaining 20 areas will be automatically put in the control group B.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. Blinding was done in two levels: The first level: the dermatologist examining the effectiveness rate on each side of the treated face, who was different from the main dermatologist directing the study, and was not aware of the type of treatment performed on each side of the face. second level: data analyzer, who was not given information about the type of treatment performed on each side of the face and their possible effectiveness.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Ebne Sina Ave, Tahmasb Abad Blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-11-08, 1399/08/18

Ethics committee reference number

IR.KMU.AH.REC.1399.105

Health conditions studied**1****Description of health condition studied**

Periorbital hyperpigmentation

ICD-10 code

L81.4

ICD-10 code description

Other melanin hyperpigmentation

Primary outcomes**1****Description**

Severity of periorbital hyperpigmentation

Timepoint

At the begining of the study (before intervention) and 1

and 3 months after intervention
Method of measurement
Using Patient and Physician Global Assessment score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intra dermal injection of 0.5cc tranexamic acid and 0.5cc vitamin C into the infraorbital region in 3 session with 3-week intervals.(at the beginning of the study, general explanations about how to perform the work and after care were provided to all volunteer patients participating in the study. 0.5cc of 5cc ampoules of tranexamic acid from Caspian Tamin Iran Company along with 0.5cc of a 5cc ampoule of Vitamin C from Elixir Company was mixed in a 1cc BD syringe and injected intradermally into the dark areas around the eyes at an angle of 15-30 degrees (the desired points at a distance of 0.5-1cm) considered and 0.1cc was injected at each point).This treatment was done for three sessions, with an interval of three weeks.

Category

Treatment - Drugs

2

Description

Control group: Intra dermal injection of 1cc platelet rich plasma into the infraorbital region in 3 session with 3-week intervals. (At first, general explanations about how to perform the work and after care were given to all volunteer patients participating in the study. 5 cc of blood was taken from each patient. Then the sample was centrifuged at 1500 revolutions per minute for ten minutes. It was centrifuged. The clear plasma placed on the surface was separated and 1 cc of it was transferred to a 1 cc BD syringe. The injection was done at an angle of 15-30 degrees, intradermally to the dark areas around the eyes. (The desired points were considered with a distance of 0.5-1cm and 0.1cc was injected at each point). This treatment was done for three sessions, three weeks apart.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Behzad Iranmanesh

Street address

Afzalipour hospital, Imam highway, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

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?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Behzad Iranmanesh

Position

Assistant professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

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