Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Plasma-rich platelet veruss carboxytherapy for the treatment of periocular hyperpigmentation; which approach is superior?

Protocol summary

Study aim
Comparison effect between carboxytherapy and plasma rich platelet for treatment of periocular hyperpigmentation

Design
Clinical trial with parallel groups, single blind, non random in 20 patient

Settings and conduct
The study population was selected through convenience sampling until achieving the aimed number of the cases. After that, each side of the face was randomly treated with whether A approach or B approach. Carboxytherapy was considered as group A, and plasma-rich platelet as group B. facial side allocation to the approaches was performed using Random Allocation software in a way that each side of the face was provided with number one or two. The side with the random number one underwent Carboxytherapy, and number two underwent PRP. The injections were performed intradermally in the space lying within a centimeter under lower eyelid and amount of 0.2-0.3 cc in each point of injection. The two dermatologists who interpreted the photographs were blinded to the type of approach used for each side of the face. Besides, in order to prevent bias, they were unaware that a photograph was taken preoperatively or postoperatively

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 20-65 y/o; 3-4 Fitzpatrick skin type. Exclusion criteria: history of internal medical diseases; history of platelet disorders; smoking; lactating or pregnancy; patients' unwillingness of participation in the study; use of other therapeutic approaches.

Intervention groups
In the current clinical trial, number of 20 patients with POH underwent carboxytherapy was performed by intradermal injection carbon-dioxide gas once weekly for six weeks. The PRP treatment was performed by intradermal injection of PRP in periorbital space every two weeks for three times.

Main outcome variables
Score of periocular hyperpigmentation

General information

Reason for update

Acronym
PRP: Plasma rich platelet

IRCT registration information
IRCT registration number: **IRCT20210130050181N1**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-13, 1399/11/25**
Update count: **0**

Registration date
2021-02-13, 1399/11/25

Registrant information

Name
Akramsadat Amiri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3653 3805

Email address
sadatamiri1367@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-08, 1399/11/20

Expected recruitment end date
2021-04-09, 1400/01/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Plasma-rich platelet veruss carboxytherapy for the treatment of periocular hyperpigmentation; which approach is superior?

Public title

Plasma-rich platelet veruss carboxytherapy for the treatment of periocular hyperpigmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

3-4 Fitzpatrick skin type Age 20-65 years old

Exclusion criteria:

History of internal medical diseases(e.g., no previous history of cardiac, liver and/or renal diseases, diabetes mellitus, and thyroid dysfunction History of platelet disorders and/or coagulopathy Smoking and/or addiction Lactating or pregnancy Patients' unwillingness of participation in the study Use of other therapeutic approaches

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each side of the face was randomly treated with PRO and carboxytherapy

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The two dermatologists who interpreted the photographs were blinded to the type of approach used for each side of the face. Besides, in order to prevent bias, they were unaware that a photograph was taken preoperatively or postoperatively.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib Ave.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.MUI.MED.REC.1397.300

Health conditions studied

1

Description of health condition studied

Periocular hyperpigmentation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score of periocular hyperpigmentation

Timepoint

Before and within eight weeks after study performance

Method of measurement

Visual analog scale score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Carboxytherapy was performed by injection of carbon dioxide gas once weekly for six weeks. The amount of 5cc of CO_2 was intradermally injected at the one-third lateral part of each eyelid using a 30-gauge needle with a velocity of 50 cc per minute.

Category

Treatment - Other

2

Description

Intervention group: The other side of the face was treated using one cc of PRP injected in periorbital space using an insulin syringe every two weeks for three times. The injections were performed intradermally in the space lying within a centimeter under lower eyelid and amount of 0.2-0.3 cc in 1.5-2 mm depth in each point of injection. The sites of injections were 1 centimeter apparent to the other ones.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al_Zahra hospital

Full name of responsible person

Akram Sadat Amiri

Street address

Al_Zahra hospital, Soffe Ave.

City

Isfahan

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8174675731

Phone

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Email

sadstamiri1367@Gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo

Street address

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Email

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Akram Sadat Amiri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fateme Mokhtari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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f_mokhtari2004@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Akram Sadat Amiri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

Street address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to security of patient secret

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