

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy of Autologous Platelet Rich Plasma Combined with Ablative Carbon Dioxide Fractional Resurfacing laser vs Ablative Carbon Dioxide Fractional Resurfacing laser alone in Acne scar treatment

Protocol summary

Summary

This project is a random double blind clinical trial study due to be carried out in clinics and educational establishments supervised by Isfahan University of Medical Sciences during 1393 H. The subjects are sixteen patients afflicted by dominant rolling and boxcar scars who have not been laser-treated for twelve, or recieved isotretinoin for six months. The division of their faces will be twofold (right and left parts) and the subjects randomly put into two groups of sixteen each. The first group is to be treated with Prp and fractional co2 laser; the second with only fractional co2 laser. In the latter group normal saline will be injected in place of PRP to avoid any awareness of the procedure in the patients. This treatment will be effected twice with a one month interval in between. The patients will be required to take photographs serially before and one month after the first treatment session and four months after the second. The photographs will be scored by two dermatologists using the quartile scale. Evaluation of adverse effects (erythem an edema) is by the patients and based on the self-assessment at days 0,2,4,6,8,15, 30 after each treatment session – and the visual analogue scale for scoring. Patient satisfaction will also be scored by quartile scale. Data analysis is with SPSS software.

General information

Acronym

PRP:Platelet Rich Plasma

IRCT registration information

IRCT registration number: **IRCT2014080218648N1**

Registration date: **2014-10-11, 1393/07/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-11, 1393/07/19

Registrant information

Name

Shima Keyvan

Name of organization / entity

Isfahan university of medical science

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Recruitment status

Recruitment complete

Funding source

Deputy of research of Isfahan University of Medical Sciences.

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2014-10-07, 1393/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of Autologous Platelet Rich Plasma Combined with Ablative Carbon Dioxide Fractional Resurfacing laser vs Ablative Carbon Dioxide Fractional Resurfacing laser alone in Acne scar treatment

Public title

Efficacy of Platelet Rich Plasma and fractional co2 laser

in treatment of acne scar of face

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Patients who have polymorphic and mixed acne scar (dominantly rolling and boxcar types ,less than 20 ice pick type and no hypertrophic or keloid type) 2. Patients who don't have other skin disease 3. Patients who have skin types 3-5 in Fitzpatrick scale 4. Willingness for participation in the study and signing the consent form. Exclusion criteria: 1. Known allergic reaction to components of study treatment that leads to unfinished study 2. Patient is unwilling to continue the study 3. Co-treatment with other methods 4. History of keloid formation 5. Any kind of active inflammation 6. Oral isotretinoin use within the preceding 6 months 7. Diabetes, collagen vascular disease 8. Ablative or nonablative laser skin resurfacing within the preceding 12 months, 9. Pregnancy or lactation 10. If patient doesn't follow the study .

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 32

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan

City

Isfahan

Postal code

Approval date

2014-01-08, 1392/10/18

Ethics committee reference number

393020

Health conditions studied

1

Description of health condition studied

acne scar

ICD-10 code

L90.5

ICD-10 code description

scar condition and fibrosis of skin

Primary outcomes

1

Description

Atrophic scar of acne

Timepoint

Before and after the intervention

Method of measurement

Photography of scar before beginning ,1 month after first session of treatment and 4 months after second session of treatment

Secondary outcomes

1

Description

Clinical improvement of scar

Timepoint

1 month after first session of treatment and 4 months after second session of treatment

Method of measurement

Self-assessment by the patients and visual analogue scale

2

Description

treatment associated adverse events(erythema and edema)

Timepoint

days 0, 2, 4, 6, 8, 15, and 30 after each session of treatment

Method of measurement

serial photography, inspection by dermatologist and visual analogue scale

3

Description

Patients satisfaction

Timepoint

1 month after first session of treatment and 4 months after second session of treatment

Method of measurement

Quartile scale

Intervention groups

1

Description

20cc patient blood will be taken and mixed with anticoagulant in a ratio of 1:10 (anticoagulant/blood). The mixture will then be centrifuged at a speed of 2,000 rpm for 3 minutes and the residue will be centrifuged again with concentration kit for 5 minutes at 5,000 rpm. 4cc PRP will finally be obtained. The PRP is to be obtained using a commercially available two-part system (Proslys PRP, T•Cell Bio Inc., Seoul, South Korea) and mycells kit produced by South Korea. One side of the face (scar site) will receive 0.2mL of PRP at 2cm interval immediately after laser treatment. Participants will then be instructed to compress their faces with gauze for 15 to 20 minutes. Control group: The other side of the face (scar site), will receive 0.2mL of normal saline at 2cm interval on the scar site immediately after laser treatment. Participants will be instructed to compress their faces with gauze for 15 to 20 minutes.

Category

Other

2

Description

Intervention group: The intended procedure is to be a pass of ablative fractional co2 laser – a setting of laser power: 25, dot cycle (duration): 3, energy: 30 mj, pixel pitch: 1, and ablation depth: 600 µm -on one side of the face. Control group: The intended procedure is to be, in similar fashion to the intervention group, a pass of ablative fractional co2 laser – a setting of laser power: 25, dot cycle (duration): 3, energy: 30 mj, pixel pitch: 1, and ablation depth: 600 µm- on the other side of the face

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

AL-Zahra hospital

Full name of responsible person

Dr Shima Keyvan

Street address

Department of Dermatology, Al-Zahra hospital, Soffeh Blvd, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan 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

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Diseases and leishmaniasis research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Dr shima keyvan

Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty