

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Fractional Erb-YAG laser versus combined fractional Erb-YAG laser and local platelet-rich plasma in facial rejuvenation, in patients referred to Shohadaye Tajrish hospital, 2019-2020

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determination and comparison of the efficacy of topical erbium fractional laser and topical PRP simultaneously in the treatment of facial wrinkles based on skin elasticity measurement by Reviscometer

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

Registration date

2020-03-30, 1399/01/11

Design

The present study is a randomized double-blind face-split Trial clinical trial. The study design and type of patient allocation will be in parallel.

Registrant information

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Name of organization / entity

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Settings and conduct

The present study is a randomized double-blind face-split Trial clinical trial that will be performed in one year at Shohadaye Tajrish Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1- Women 60-60 years 2- Mild to moderate wrinkles at rest Exclusion criteria: 1. Male gender 2. Under 35 and over 60 years of age 3. Breastfeeding and pregnancy 4- Perform other facial cosmetic procedures like Botox, Dermabrasion, Chemical Peeling and Face Lift in the past 6 months 5- Oral isotretinoin in the past 6 months 6- History of colloid formation 7. Not willing to participate in the study

Recruitment status

Recruitment complete

Funding source

Intervention groups

One half was randomly assigned (using a random number table) to be treated with an Er: YAG laser with normal saline without any therapeutic effect, and the other half was treated with an Er: YAG laser with PRP.

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

The rate of skin rejuvenation

Scientific title

Fractional Erb-YAG laser versus combined fractional Erb-YAG laser and local platelet-rich plasma in facial rejuvenation, in patients referred to Shohadaye Tajrish hospital, 2019-2020

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200107046041N1**

Registration date: **2020-03-30, 1399/01/11**

Public title

Fractional Erb-YAG laser versus combined fractional Erb-YAG laser and local platelet-rich plasma in facial rejuvenation

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Women 60-35 years Mild to moderate wrinkles at rest

Exclusion criteria:

Male gender Under 35 and over 60 years of age
Breastfeeding and pregnancy Perform other facial cosmetic procedures like Botox, Derm abrasion, Chemical Peeling and Face Lift in the past 6 months Oral isotretinoin in the past 6 months
6- History of colloid formation Not willing to participate in the study

Age

From **35 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization using Random Number Table

Blinding (investigator's opinion)

Double blinded

Blinding description

The ambiguity in this study would be that both the researcher (and the laser operator) and the patients were unaware of the treatment or treatment group received. The method of double blinding would be to ask a third party other than the researcher and operator to cover the saline and PRP tubes with colored labels (each a special color) so that neither the researcher nor The operator of the device used the material and diagnose it based on color.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

ir.sbm.u.src.rec.1398.022

Health conditions studied

1

Description of health condition studied

Skin Rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Wrinkle removal

Timepoint

Patients are monitored for reviscometer and digital imaging in the first session (baseline), second and third treatment, and 3 months after the last laser session.

Method of measurement

The results are evaluated qualitatively and quantitatively: In the qualitative method, the patients are photographed with the same digital camera before the start of the project and then at each visit. The improvement is in the percentage of zero to one hundred. Finally, the rate of recovery is defined as No response (less than 10%), mild response (10-25%), moderate response (25-50%) and good response (50-75%) Excellent response (over 75%) Is. Quantitative testing is done by the multi probe adapter system MPA5. MPA5 is a device for checking the suitability of various biophysical parameters of the skin. Using Reviscometer based on Resonance running time acoustic waves and mechanical properties of skin are measured skin resonance time and thus determine the biological age of the skin at different angles.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: One half of face PRP 10cc 3session 1month interval with fractional erb yag laser total fluence 60 j on cm2 pulse duration400 microsecond

3session 1month interval

Category

Treatment - Devices

2

Description

intervention group 2:Another half of face fractional erb yag laser total fluence 60 j on cm2 pulse duration400 microsecond 3session 1month interval

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr Arash Rahbar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Robati

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Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Arash Rahbar

Position

resident

Latest degree

Medical doctor

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