Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

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.

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

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.

Main outcome variables
The rate of skin rejuvenation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200107046041N1**
Registration date: **2020-03-30, 1399/01/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-30, 1399/01/11**
Update count: **0**

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

Registrant information

Name
Hamideh Moravej farshi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2274 1507

Email address
hamidehmoravej@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

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

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

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 months6- 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.sbmu.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

Street address

Shahrdari

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

Pr_shohada@sbmu.ac.ir

Web page address

http://shmc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reza Robati

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

Dean.medicalschool@sbmu.ac.ir

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

Dermatology

Street address

shahrdari

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

Arashrahbar10@gmail.com

Person responsible for scientific 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

Dermatology

Street address

Shahrdari

City

Tehran

Province

Tehran

Postal code
1989934148
Phone
+98 21 25719
Email
Arashrahbar10@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash Rahbar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Shahrdari
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Arashrahbar10@gmail.com

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