

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 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

##### Name

Hamideh Moravej farshi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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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

**Street address**

Shahrdari

**City**

Tehran

**Province**

Tehran

**Postal code**

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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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**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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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Province**

Tehran

**Postal code**

1989934148

**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