

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Efficacy and safety of fractional Er:YAG versus microneedling in treatment of facial rhytides in 45-75 years old patients

#### Protocol summary

##### Study aim

Determination of the effectiveness of microneedling compared to the fractional Laser Er:YAG in the treatment of face wrinkles based on the measurement of the resonance time of the skin by reviscometer.

Determination of microneedling safety in comparison with fractional laser Er:YAG in the treatment of face wrinkles.

##### Design

We performed a randomized controlled trial in a split face design. 36 patients were included. Patients were assigned to receive three monthly treatments on each side of the face, one side with dermapan(microneedling) and the other with fractional Er:YAG laser. The ER:YAG laser with a 7-micron spot, a 350 microsecond pulse and a total fluence of 3.12 J per cm<sup>2</sup> and an energy pulse of 1 to 1.2 J with a fractional handpiece and dermapan use. Patients in the first, second, third, and 3 months follow-up sessions are evaluated by MPA-9(multi probe adaptore-9) and digital photography. Two board-certified dermatologists were asked to score the clinical outcome regarding the improvement of wrinkles and clinical appearance. Degree of clinical improvement was defined as the percentage of improvement: no response, mild response, moderate response, good response, and excellent response. A quantitative survey of the biomechanical parameters is done by a multiprobe device. For subjective evaluation, patient satisfaction is measured through the Facial Lines Outcomes Questionnaire. All undesired effects of the procedures such as edema, pain, burning, itching, erythema, were recorded. The aim of this study was to compare the safety and efficacy of microneedling and fractional ER:YAG laser in the treatment of facial wrinkles and possible complications, patient satisfaction from each of the methods, down time and the changes recorded It will be compared by a MPA-9 device.

##### Settings and conduct

The location of the study is dermatology clinic of

Shohada'e Tajrish Hospital. Study approved by the ethical committee of Shahid Beheshti University. The ER:YAG laser used in this study has a fractional handpiece and dermapan. The treatment area was thoroughly cleaned before the procedure, lidocaine ointment was applied at least 30 min before the treatment. Eyes were covered with a moist gauze. Laser therapy was done from the hairline to the chin. Zinc oxide ointment was applied to the treatment areas immediately after the procedure. Patients were asked to re-apply zinc oxide ointment as needed. Also, they were advised to stay away from direct sun exposure. Patients were assigned to receive three monthly treatments on each side of the face, one with dermapan and the other with fractional Er:YAG laser. Photographs were taken at baseline, before each treatment session, and 3 months after the final treatment. Two board-certified dermatologists were asked to score the clinical outcome regarding the improvement of wrinkles, skin texture. The wrinkle improvement was calculated with the use of visual analog scale (VAS). Degree of clinical improvement was defined as the percentage of improvement: no response (less than 10%), mild response (10-25%), moderate response (25-50%), good response (50-75%), and excellent response (more than 75%). Outcomes were evaluated by investigators at each session and 3 months after the third treatment. A quantitative study of the biomechanical parameters is performed by a multiprobe device. For subjective evaluation, patient satisfaction was measured using the Facial Lines Outcomes Questionnaire as a percentage of satisfaction from 0 to 100. All undesired effects of the procedures such as edema, pain, burning, itching, erythema, blister, bleeding, crust, hypopigmentation, hyperpigmentation, scars, and atrophy were recorded. In summary, the aim of this study was to compare the safety and efficacy of both microneedling and fractional ER:YAG laser in the treatment of facial wrinkles and possible complications, satisfaction of patients from each of the methods, the time needed to return the skin to the original state and The changes recorded by the MPA-9 will be compared.

## Participants/Inclusion and exclusion criteria

Subjects between 45 and 75 years old with mild to moderate facial skin rhytides at rest were included. People with: 1-Pregnant or breast feed 2-History of cuagulopathy disorder or drug 3-Facial active Infection 4-Inability to fallow up visit 5-Connective tissue disorder 6-History of skin cancer on face 7-Unrealistic expectation 8-Cosmetic procedureds performed on the face in the last 6 month 9-Fitzpatrick skin phototype >III 10-Sensitivity to lidocain 11-Use isotretinoin in the last 6 month 12-History of keloid 13-Use photosensitive drug such gold and tetracyclin were excluded.

## Intervention groups

In patients who have 45 to 75 years old with mild to moderate facial skin wrinkles at rest apply fractional ER:YAG laser at one side of the face and microneedlig in the other half of the face Monthly up to three times.

## Main outcome variables

Photographs were taken at baseline, before each treatment session, and 3 months after the final treatment. Two board-certified dermatologists were asked to score the clinical outcome regarding the improvement of wrinkles and skin texture. Degree of clinical improvement was defined as the percentage of improvement: no response (less than 10%), mild response (10 to 25%), moderate response (25 to 50%), good response (50 to 75%), and excellent response (more than 75%). A quantitative study of the of biomechanical parameters is performed by a multiprobe adapter-9 device. Measurements are carried out at different angles(0, 90, 180, 270) and based on the average calculated number of the comparison. For subjective evaluation, patient satisfaction was measured using the Facial Lines Outcomes Questionnaire as a percentage of satisfaction from 0 to 100. All undesired effects of the procedures such as edema, pain, burning, blister, bleeding, erythema, crust, hypopigmentation, hyperpigmentation, scars, and atrophy were recorded. In summary, the aim of this study was to compare the safety and efficacy of microneedling and fractional ER:YAG laser in the treatment of facial wrinkles and Improvement of wrinkles, possible complications, patient satisfaction from each of the methods, the time needed to return the skin to the initial state(down time) and Changes recorded by the MPA-9, including the amount of transepidermal water loss and the time of resonance of the skin will be compared.

## General information

### Reason for update

### Acronym

### IRCT registration information

IRCT registration number: **IRCT20160820029436N3**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

### Registration date

2018-02-04, 1396/11/15

## Registrant information

### Name

Behnaz Hamedani

### Name of organization / entity

Shahid Beheshti university Shohada'e Tajrish hospital skin research center

### Country

Iran (Islamic Republic of)

### Phone

+98 21 2274 1507

### Email address

behnazhamedani@sbm.ac.ir

## Recruitment status

### Recruitment complete

## Funding source

Deputy of Research and Technology, Shahid Beheshti University of Medical Sciences

## Expected recruitment start date

2018-01-05, 1396/10/15

## Expected recruitment end date

2018-02-09, 1396/11/20

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Efficacy and saftey of fractional Er:YAG versus microneedling in treatment of facial rhytides in 45-75 years old patients

## Public title

Efficacy and saftey of fractional Er:YAG versus microneedling in treatment of facial rhytides

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 45 to 75 Mild to moderate wrinkling on the face

### Exclusion criteria:

Pregnant or breast feed History of cuagulopathy disorder or drug Facial active Infection Inability to fallow up visit connective tissue disorder History of skin cancer on face Unrealistic expectation Cosmetic procedureds performed on the face in the last 6 month Fitzpatrick skin phototype >III Sensitivity to lidocain Use isotretinoin in the last 6 month History of keloid Use photosensitive drug such gold, tetracyclin

## Age

From **45 years** old to **75 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **36**

More than 1 sample in each individual

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

Laser or microneedling on each side of the face

Actual sample size reached: **36**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

In individuals entered into the study, one half of the face is randomly studied by laser and the other half by microneedling.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

In individuals entered into the study, one half of the face is randomly studied by laser and the other half by microneedling. Patients are unaware of the nature of the action taken on each side of the face. Assessment practitioners are also unaware of the action taken, for example, they do not know in Patient A that they are on the right side of the laser or microneedling.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Controlled Split-Face Clinical Trial

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Skin Research Center, Shahid Beheshti University of Medical Sciences

##### Street address

Shohada'e Tajrish Hospital, Tajrish Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1989934148

#### Approval date

2016-10-23, 1395/08/02

#### Ethics committee reference number

ir.sbm.u.osrc.rec.1395.26

## Health conditions studied

### 1

#### Description of health condition studied

Facial skin wrinkles

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Transepidermal water loss

#### Timepoint

Before each treatment session and then after three month of treatment

#### Method of measurement

Measurement of skin biophysical properties by MPA-9 device

### 2

#### Description

Skin hydration

#### Timepoint

Before each treatment session and then after three month of treatment

#### Method of measurement

By dermatologist and using MPA-9 device

### 3

#### Description

Patient satisfaction

#### Timepoint

Before each treatment session monthly and then after three month of treatment

#### Method of measurement

Asking the patient

### 4

#### Description

Downtime

#### Timepoint

Before treatment every month and then after three month of treatment

#### Method of measurement

By dermatologist

### 5

#### Description

Clinical assessment of improvement

#### Timepoint

Before treatment every month and then after three month of treatment

#### Method of measurement

By dermatologist by comparing the patient's pictures

### 6

#### Description

skin resonance time

#### Timepoint

Before treatment every month and then after three month of treatment

#### Method of measurement

By dermatologist and using reviscometer

## Secondary outcomes

**1**

**Description**

Pain

**Timepoint**

Before each treatment session monthly

**Method of measurement**

Asking the patient

**2**

**Description**

Burning

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient

**3**

**Description**

Erythema

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient

**4**

**Description**

Edema

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient

**5**

**Description**

Bulla formation

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient

**6**

**Description**

Bleeding

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient

**7**

**Description**

Dispigmentation

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient and by dermatologist

**8**

**Description**

Scar formation

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient and by dermatologist

**9**

**Description**

Skin atrophy

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient and by dermatologist

**10**

**Description**

Crust formation

**Timepoint**

Before each treatment session

**Method of measurement**

Asking the patient and by dermatologist

## Intervention groups

**1**

**Description**

In 45 to 75 years old patients with mild to moderate facial skin wrinkles, a half-face is subjected to a microneedling monthly up to three times and its efficacy and safety are examined by the methods described in the study method.

**Category**

Treatment - Devices

**2**

**Description**

Control group: In 45 to 75 years old patients with mild to moderate facial skin wrinkles, a half-face is subjected to a Fractional ER:YAG laser (the ER:YAG laser with a 7-micron spot, a 350 microsecond pulse and a total fluence of 3.12 J per cm<sup>2</sup> and an energy pulse of 1 to 1.2 J with a fractional handpiece) monthly up to three times and its efficacy and safety are examined by the methods described in the study method.

**Category**

Treatment - Devices

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shohada'e Tajrish Hospital

**Full name of responsible person**

Behnaz Hamedani

**Street address**

Shohada'e Tajrish Hospital, Tajrish Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 1507

**Fax**

+98 21 2274 4393

**Email**

hamedanibehnaz@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Deputy of Research, Shahid Beheshti University of  
Medical Sciences

**Full name of responsible person**

Dr Amirmohsen Ziaei

**Street address**

Shahid Beheshti University of Medical Sciences,  
Velenjak

**City**

Tehran

**Province**

Tehran

**Postal code**

193954719

**Phone**

+98 21 2243 9951

**Email**

mpd@sbm.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Deputy of Research, 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**

Skin Research Center of Shahid Beheshti University

**Full name of responsible person**

Behnaz Hamedani

**Position**

Dermatology Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Shohada'e Tajrish Hospital, Tajrish Square

**City**

Tehran

**Province**

Tehran

**Postal code**

4571935935

**Phone**

+98 24 3552 5289

**Fax**

**Email**

hamedanibehnaz@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Skin Research Center of Shahid Beheshti University

**Full name of responsible person**

Reza Robati

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Shohada'e Tajrish Hospital, Tajrish Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 1508

**Fax**

**Email**

rezarobati@sbm.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Skin Research Center of Shahid Beheshti University

**Full name of responsible person**

Behnaz Hamedani

**Position**

Dermatology Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Shohada'e Tajrish Hospital, Tajrish Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 24 3552 5289

**Fax****Email**

hamedanibehnaz@gmail.com

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Adaptation of information recorded by the reviscometer and the clinical response along the photos of the camera, and the degree of satisfaction of the participants with the procedures performed in different patients according to skin phenotype and the response to each of the two methods listed in the study, published in the separate table

**When the data will become available and for how long**

After completing the treatment and patients' follow up

**To whom data/document is available**

Researchers of academic institutions

**Under which criteria data/document could be used**

All dermatologists can access the data to use procedure for their patients.

**From where data/document is obtainable**

Refer to the Dermatology Research Center at Shohada e Tajrish Hospital in Tehran. Accountability will be done by Dr. Behnaz Hamedani

**What processes are involved for a request to access data/document**

The request is submitted in writing.

**Comments**