Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and saftey 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 2 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 prob 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 committiee of Shahid Beheshti University. The ER:YAG laser used in this study has a fractional handpiece and dermapan. The treatment area was thoroughly cleand before the procedure, lidocain ointment was aoolied 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 procedures 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 micrneedling 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

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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 procedures 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 micronidling.
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 micronidlikg, 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 micronizing.
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.sbmu.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 tretment 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 esch treatment session monthly
Method of measurement
Asking the patient

2

Description
Burning
Timepoint
Before esch treatment session
Method of measurement
Asking the patient

3

Description
Erythema
Timepoint
Before esch treatment session
Method of measurement
Asking the patient

4

Description
Edema
Timepoint
Before esch treatment session
Method of measurement
Asking the patient

5

Description
Bulla formation
Timepoint
Before esch treatment session
Method of measurement
Asking the patient

6

Description
Bleeding
Timepoint
Before esch treatment session
Method of measurement
Asking the patient

7

Description
Dispigmentation
Timepoint
Before esch treatment session
Method of measurement
Asking the patient and by dermatologist

8

Description
Scar formation
Timepoint
Before esch treatment session
Method of measurement
Asking the patient and by dermatologist

9

Description
Skin atrophia
Timepoint
Before esch treatment session
Method of measurement
Asking the patient and by dermatologist

10

Description
Crust formation
Timepoint
Before esch 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 time 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 2 and an energy pulse of 1 to 1.2 J with a fractional handpiece) monthly up to three time 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

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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

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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
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

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Full name of responsible person
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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' fallow 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