Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and side effects of Nd:YAG versus fractional Er:YAG in facial rejuvination

Protocol summary

Summary

Objrctive: Efficacy and safety of fractional Co2 laser versus fractional Er:YAG in treatment of facial rhytides determination study .Design:randomized,double blined,parallel,phase1 clinical trial. Methodology: Target selection:Patients referring to Shohadaye Tajrish Educational Hospital a) Inclusion criteria:1)females between 35 and 75years of age 2)patients with mild to moderate facial rhytides at rest Exclusion criteria included: 1)males 2)females younger than 35 yerars old 3)pregnancy and lactatation 4)cosmetic procedures affecting the treatment area (e.g.,botulinum toxin, dermabrasion, chemical peeling, laser surgery, or face-lift) within the last 6months 5) oral isotretinoin within the last 6months 6) history of keloid formation 7)connective tissue disorders,8)major underlying disease,9)diabetes, 10)uncontrolled hypertension, 11)active infection in face area,13) personal history of skin cancer in face,14)unrealistic expectation,15)sensitivity to tetracaine or lidocaine Target sample size:35 b) Study interventions:Patients were randomly assigned to receive treatment on each side of face , one with a long pulsed Nd:YAG and one with a fractional Er:YAG laser. c)Time of the intervention:3 treatment sessions with 1 month interval for each patient d)Study outcome:The evaluation both before each treatment session and 3months after the last one will be done with reviscometer and digital photography as well as assessment of side effects (eg.,pain,stinging,pruritis,redness,bulla,bleeding,crust formation,hypopigmentation,hyperpigmentation,scar,atrophy)will be performed .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120320468N3**
Registration date: **2016-04-03, 1395/01/15**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name
Reza Robati
Name of organization / entity
Skin Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Skin research center,Shahid Beheshti University of medical Science.

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and side effects of Nd:YAG versus fractional Er:YAG in facial rejuvination

Public title

Efficacy of laser in facial rejuvination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:females between 35 and 75years of age ;patients with mild to moderate facial rhytides at rest Exclusion criteria :males;females younger than 35 yerars old;pregnancy and lactatation;cosmetic procedures affecting the treatment area (e.g.,botulinum toxin,dermabrasion, chemical peeling, laser surgery, or face-lift)within the last 6months;oral isotretinoin within the last 6months; history of keloid formation,connective tissue disorders,major underlying disease,diabetes, uncontrolled hypertension, active infection in face area, personal history of skin cancer in face,unrealistic expectation,sensitivity to tetracaine or lidocaine

Age

From **35 years** old to **75 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committeeShahid Beheshti University of Medical Sciences

Street address

th Floor ,Shahid Beheshti university of medical sciences, Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran.

City

Tehran

Postal code

198396-3113

Approval date

2015-12-13, 1394/09/22

Ethics committee reference number

.IR. SBMU.RAM.REC.1394.418

Health conditions studied

1

Description of health condition studied

Skin Rejuvination

ICD-10 code

L98.8

ICD-10 code description

Other specified disorders of skin and subcutaneous tissue

Primary outcomes

1

Description

Skin Elasticiy

Timepoint

before intervention,before each laser sessions,3 months after last laser

Method of measurement

resonance running time/reviscometer

2

Description

improvement of facial rythides

Timepoint

before intervention,before each laser sessions,3 months after last laser

Method of measurement

rate of improvement measured by comparing photograph by a dermatologist

3

Description

patient satisfaction

Timepoint

1month after session 1&2-three month after session3

Method of measurement

questionare

Secondary outcomes

1

Description

Duration of side effects

Timepoint

one week after each session

Method of measurement

number of days

2

Description

side effects(pain-burning and stinging-erythem-edema-bulla-bleeding-crust formation-hypopigmentation-hyperpigmentation-scar-atrophy)

Timepoint

one week after each session

Method of measurement

patient questionnaire,examination by a dermatologist

Intervention groups

1

Description

Topical anesthetic gel is applied to both sides of face and left for 30minutes. The patient's eyes are covered with a shield during the entire procedure. Patients are randomly assigned to receive treatment with a fractional Er-YAG Laser on one side of face ;which is focused to a spot size of approximately 250 micrometer in diameter ,the pulse duration of 400microseconds and total fluence of 60J/cm2 .Three treatment sessions with 1 month interval for each patient will be done.The evaluation both before each treatment session and 3months after the last one will be done with reviscometer and digital photography .

Category

Other

2

Description

Topical anesthetic gel is applied to both sides of face and left for 30minutes. The patient's eyes are covered with a shield during the entire procedure. Patients are randomly assigned to receive treatment with a Nd: YAG Laser on one side of face ;which is focused to a spot size of approximately 5-10 micrometer in diameter ,the pulse duration of 0.3 -20 milliseconds and fluence from 10 to 25 J/cm2.Three treatment sessions with 1 month interval for each patient will be done.The evaluation before each treatment session and 3months after the last one will be done with the reviscometer and digital photography .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-E- Tajrish Educational Hospital

Full name of responsible person

Dr Reza Robati-Assistant Professor of Dermatology

Street address

Skin Research Center, Shohada-E- Tajrish Educational Hospital, Qods Sq. , Tehran, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin Research Center, Shahid Beheshti University of Medical Science

Full name of responsible person

Dr. Parviz Toosi

Street address

Shahid Beheshti university of medical sciences, Velenjak, Shahid Chamran Highway, Tehrān, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Skin Research Center, Shahid Beheshti University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Skin Research Center

Full name of responsible person

Sahar.dadkhahfar@gmail.com

Position

Resident of Dermatology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty