Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety of fractional Co2 laser versus fractional Er:YAG in treatment of facial rhytides

Protocol summary

Summary

Study purpose: 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 60years 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 Target sample size:40 b) Study interventions:Patients were randomly assigned to receive treatment on each side of face , one with a fractional CO2 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: **IRCT2014122820468N1**
Registration date: **2015-03-26, 1394/01/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name
Reza Robati
Name of organization / entity
Skin Research Center
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Recruitment status

Recruitment complete

Funding source

Dermatology Research Center of Shahid Beheshti University of Medical Science

Expected recruitment start date

2015-01-15, 1393/10/25

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of fractional Co2 laser versus fractional Er:YAG in treatment of facial rhytides

Public title

Efficacy of laser in skin rejuvination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:females between 35 and 60years 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

Age

From **35 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

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

Skin Research Center,Shahid Beheshti University of Medical Science

Street address

The SBMU SRC (Skin Research Center),Shohada-E-Tajrish Educational Hospital,Qods Sq. ,Tehran, Iran

City

Tehran

Postal code

Approval date

2013-11-18, 1392/08/27

Ethics committee reference number

192/93

Health conditions studied

1

Description of health condition studied

Skin rejuvenation

ICD-10 code

L98.8

ICD-10 code description

Other specified disorders of skin and subcutaneous tissue

Primary outcomes

1

Description

skin elasticity

Timepoint

before treatment_before each session_3month after the last session

Method of measurement

resonance running time/reviscometer

2

Description

rhytides improvement

Timepoint

before treatment_before each session_3month after the last session

Method of measurement

improvment percentage_comparing digital photoghraphes by dermatologist

3

Description

Patient satisfaction

Timepoint

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

Method of measurement

percentage- Patient satisfaction questionnaire

Secondary outcomes

1

Description

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

Timepoint

one week after each treatment session

Method of measurement

patient evaluation with questionnaire-dermatologist evaluation

2

Description

side effects lasting

Timepoint

until one week after each treatment

Method of measurement

day

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 Co2 Laser on one side of face ;which is focused to a spot size of approximately 120 micrometer in diameter ,the pulse duration of 10 milliseconds and pulse energy varies from 5 to 70mJ .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

Treatment - 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 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

Treatment - 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

The SBMU SRC (Skin Research Center),Shohada-E-Tajrish Educational Hospital,Qods Sq. ,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science-Skin Research Center

Full name of responsible person

Dr Parviz Toosi

Street address

Iran, Tehran, Velenjak St. , Shahid Chamran Highway

City

Tehran

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 Science-Skin Research Center

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

Elmira Asadi

Position

Assistant Resident of Dermatology

Other areas of specialty/work

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Position

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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