Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety of fractional Co2 laser versus fractional Nd:YAG in hand rejuvination

Protocol summary

Summary

Study purpose: efficacy and safety of fractional Co2 laser versus fractional Nd:YAG in hand rejuvination determination. Study design: randomized, double blind, parallel, phase1 clinical trial. Target selection: patients referring to Shohadaye Tajrish Educational Hospital. Inclusion criteria: females aged between 45 and 75 years old; patients with mild to moderate hand sun damage. Exclusion criteria: females younger than 45 years old; cosmetic procedures affecting the treatment area (e.g., chemical peeling) within the last 6 months; oral administration of isotretinoin within the last 6 months; history of keloid formation. Target sample size: 36 patients. Study interventions: patients were randomly assigned to receive treatment on each hand, one with a fractional CO2 and one with a fractional Nd:YAG laser. Time of the intervention:3 treatment sessions with 1 month interval for each patient. Study outcome: the evaluation both before each treatment session and 3 months after the last one will be done with reviscometer and digital photography as well as assessment of side effects (eg., pain, stinging, pruritus, redness, bulla, bleeding, crust formation, hypopigmentation, hyperpigmentation, scar, atrophy) will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016032020468N4**
Registration date: **2016-03-31, 1395/01/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-03-31, 1395/01/12

Registrant information

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Reza Robati
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Skin Research Center
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Recruitment status

Recruitment complete

Funding source

Dermatology Research Center, Shahid Beheshti University of Medical Science

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-09-05, 1395/06/15

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 Nd:YAG in hand rejuvination

Public title

Efficacy of laser in skin rejuvination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: females aged between 45 and 75 years old; patients with mild to moderate hand sun damage. Exclusion criteria: females younger than 45 years old; cosmetic procedures affecting the treatment area (e.g.,

chemical peeling) within the last 6 months; oral administration of isotretinoin within the last 6 months; history of keloid formation.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

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

Street address

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

City

Tehran

Postal code

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.Sbmu.RAM.REC

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, 3 months after the last session

Method of measurement

Resonance running time, reviscometer

2

Description

Rhytides improvement

Timepoint

Before treatment, before each session, 3 months after the last session

Method of measurement

Improvment percentage by comparing digital photoghraphes by dermatologist

3

Description

Patient satisfaction

Timepoint

One month after session 1; 1 to three months after session 3

Method of measurement

Patient satisfaction questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Topical anesthetic gel is applied to both hands 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 hand ;which is focused to a spot size of approximately 5 to 10 micrometer in diameter ,the on time of 0.3 to 20 milliseconds and fluence varies 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

Treatment - Other

2

Description

Topical anesthetic gel is applied to both hands 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 hand ;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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences, 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 Sciences, 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

Resident of Dermatology

Other areas of specialty/work

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Assistant Professor 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