

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

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

#### Protocol summary

##### Summary

Objective: Efficacy and safety of fractional Co2 laser versus fractional Er:YAG in treatment of facial rhytides determination study .Design:randomized,double blinded,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 years old 3)pregnancy and lactation 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 viscosimeter 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2274 1507

###### Email address

rezarobati@sbmu.ac.ir

##### 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 rejuvenation

##### Public title

Efficacy of laser in facial rejuvenation

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

Inclusion criteria: females between 35 and 75 years of age ;patients with mild to moderate facial rhytides at rest  
Exclusion criteria :males; females younger than 35 years old; pregnancy and lactation; cosmetic procedures affecting the treatment area (e.g., botulinum toxin, dermabrasion, chemical peeling, laser surgery, or face-lift) within the last 6 months; oral isotretinoin within the last 6 months; 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 committee Shahid 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 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 intervention, before each laser sessions, 3 months after last laser

#### **Method of measurement**

resonance running time/reviscometer

### **2**

#### **Description**

improvement of facial rhytides

#### **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**

1 month after session 1 & 2 - three months after session 3

#### **Method of measurement**

questionnaire

## **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-erythema-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

Tehran

## 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

##### Street address

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

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##### Phone

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Skin Research Center

##### Full name of responsible person

Dr. Reza Robati

##### Position

Assistant Professor of Dermatology

##### Other areas of specialty/work

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Skin research Center

**Full name of responsible person**

Sahar Dadkhahfar

**Position**

Assistant Resident of Dermatology

**Other areas of specialty/work****Street address**

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

**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*