

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determining the benefits and side effects of the Nd:YAG 1064 nm laser in order to achieve an effective pulse width with minimal side effects in the treatment of the face and lower limb telangiectasia

Protocol summary

Study aim

Determining the benefits and side effects of the Nd:YAG 1064 nm laser in order to achieve an effective pulse width with minimal side effects in the treatment of face and lower limb telangiectasia

Design

Phase 3 non-randomized clinical trial on 70 patients with parallel groups and single-blinded

Settings and conduct

A sample of patients with telangiectasias of the face and lower limbs who have visited the skin clinic of the Sina educational, research and therapeutic center in Tabriz will be selected and introduced to the outpatient dermatology operating room of the center for laser treatment.

Participants/Inclusion and exclusion criteria

Patients with facial telangiectasia as well as patients with lower limb telangiectasia between the ages of 18 and 50 will be included in the study. Pregnant and lactating women, patients with a history of coagulation disorders, chronic systemic liver diseases, and patients with a history of hypertrophic scars and prone to keloid will be excluded from the study.

Intervention groups

For the treatment of facial telangiectasia, two fluences of 140 and 150 J/cm² with a pulse width of 20 milliseconds and a spot size of 3 mm² and for the lower limbs from two fluences of 160 and 180 J/cm² with a pulse width of 20 milliseconds and a spot size of 5 mm square will be used.

Main outcome variables

Telangiectasia recovery rate; Patient satisfaction; Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100314003566N13**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

Registration date

2023-12-02, 1402/09/11

Registrant information

Name

Hamide Azimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-15, 1402/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the benefits and side effects of the Nd:YAG 1064 nm laser in order to achieve an effective pulse width with minimal side effects in the treatment of the face and lower limb telangiectasia		Province East Azarbaijan Postal code 5138665793 Approval date 2023-11-20, 1402/08/29 Ethics committee reference number IR.TBZMED.REC.1402.609
Public title	Benefits of Nd:YAG 1064 nm laser in the treatment of the face and lower limb telangiectasia	
Purpose	Treatment	
Inclusion/Exclusion criteria	Inclusion criteria: Patients with facial telangiectasia Patients with telangiectasia of lower limbs Consent to participate in the study Exclusion criteria: Pregnant and lactating women Patients with a history of coagulation disorders Suffering from chronic systemic liver diseases Patients with a history of hypertrophic scars and prone to keloid	
Age	From 18 years old to 50 years old	
Gender	Both	
Phase	3	
Groups that have been masked	Participant	
Sample size	Target sample size: 70	
Randomization (investigator's opinion)	Not randomized	
Randomization description		
Blinding (investigator's opinion)	Single blinded	
Blinding description	The degree of fluency, pulse width, and spot size utilized will be kept secret from patients.	
Placebo	Not used	
Assignment	Parallel	
Other design features		
Secondary Ids	empty	
Ethics committees		
<u>1</u>		
Ethics committee		
Name of ethics committee	Ethics Committee Of Tabriz University Of Medical Sciences.	
Street address	Third Floor, Central Building of Number 2, Golgasht Street	
City	Tabriz	
		Health conditions studied <u>1</u> Description of health condition studied Facial telangiectasia ICD-10 code I78.0 ICD-10 code description Hereditary hemorrhagic telangiectasia <u>2</u> Description of health condition studied Lower limb telangiectasia ICD-10 code I78.0 ICD-10 code description Hereditary hemorrhagic telangiectasia
		Primary outcomes
		<u>1</u>
		Description Recovery rate of telangiectasia Timepoint Patients will be examined at baseline, 4 weeks after the first treatment, 4 weeks after the second treatment, and 4 weeks after the last evaluation. Method of measurement Dermoscopy imaging
		<u>2</u>
		Description Patient satisfaction Timepoint Patients will be examined at baseline, 4 weeks after the first treatment, 4 weeks after the second treatment, and 4 weeks after the last evaluation. Method of measurement Interview with patients
		<u>3</u>
		Description Side effects Timepoint Patients will be examined at baseline, 4 weeks after the first treatment, 4 weeks after the second treatment, and 4 weeks after the last evaluation. Method of measurement

Including wounds, scars, erythema, hyperpigmentation, hypopigmentation and blisters, which will be evaluated by a clinical examination by a dermatologist.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients with facial telangiectasia treated with alexandrite laser with a wavelength of 1064 nm (Alexandrite ND: YAG, CA, USA) with fluence parameters of 140 and 150 J/cm² with a pulse width of 20 milliseconds and a spot size of 3 mm will be squared. Before the treatment, anesthesia will be done with a thin layer of topical gel on the surface of the skin. Also, after laser treatment, sunscreen and repair cream will be used in all patients for at least 10 days.

Category

Treatment - Devices

2

Description

Intervention group 2: Patients with lower limb telangiectasia treated with alexandrite laser with a wavelength of 1064 nm (Alexandrite ND: YAG, CA, USA) with fluence parameters of 160 and 180 J/cm² with a pulse width of 20 milliseconds and a spot size of 5 mm will be squared. Before the treatment, anesthesia will be done with a thin layer of topical gel on the surface of the skin. Also, after laser treatment, sunscreen and repair cream will be used in all patients for at least 10 days.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Sina Hospital

Full name of responsible person

Dr.Hamideh Azimi

Street address

Dermatology ward, Sina Hospital, Azadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Abolghasem Juiban

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hamide Azimi

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document

The request will be sent by email to person responsible for scientific or public inquiries.

Comments