

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of combination Erbium YAG laser and SVF therapy with Erbium YAG laser alone in the treatment of striae

Protocol summary

Study aim

Comparison of the effect of combination Erbium YAG laser and SVF therapy with Erbium YAG laser alone in the treatment of striae

Design

This study is a phase 1 clinical trial with a control group, double-blind, non-random, on 10 patients with striae. In two sessions, 1 month apart, patients in the intervention group are treated with SVF with erbium yag laser. Patients in the control group are treated with physiological serum with erbium yag laser.

Settings and conduct

This project is carried out in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences. The patients studied will be people with striae. The study will be double blind in which without informing the patient and evaluating the data from the intervention groups, patients are treated in the intervention ward with SVF with erbium yag laser and in the control ward with physiological serum treated with erbium yag laser.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of striae distension based on the diagnosis of a dermatologist; Patient satisfaction to participate in the study; Age less than 50 years and more than 18 years; Non-inclusion criteria: use of any treatment to eliminate striae in the last three months; Presence of skin lesions and diseases such as skin cancer; wart; Skin infection

Intervention groups

Intervention group: Patients are treated with SVF with erbium YAG laser. Control group: Patients are treated with physiological serum with erbium YAG laser.

Main outcome variables

striae surface; side effects; patient's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N14**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

Registration date

2022-05-02, 1401/02/12

Registrant information

Name

Sona Zare

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-19, 1401/01/30

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of combination Erbium YAG laser and SVF therapy with Erbium YAG laser alone in the

treatment of striae

Public title
The effect of erbium and SVF laser treatment in the treatment of striae

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of striae distensae based on the diagnosis of a dermatologist Patient satisfaction with the study Age less than 50 years and more than 18 years
Exclusion criteria:
Use any treatment to eliminate striae in the last three months Existence of skin lesions and diseases such as skin cancer wart Skin infection

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The assessor and the patient will not be aware of the intervention groups. Therefore, the study will be double blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz blvd.

City

Tehran

Province

Tehran

Postal code
1417653761

Approval date
2022-01-19, 1400/10/29

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.1242

Health conditions studied

1

Description of health condition studied

striae distensae

ICD-10 code

L90.6

ICD-10 code description

Atrophic disorder of skin, unspecified

Primary outcomes

1

Description

Striae size

Timepoint

Before and 3 months after the intervention

Method of measurement

biometry

Secondary outcomes

1

Description

Patient Satisfaction

Timepoint

Three months after treatment

Method of measurement

Questionnaire

2

Description

Pain

Timepoint

Injection time

Method of measurement

questionnaire

3

Description

Inflammation

Timepoint

1-5 hours after injection

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients are injected with SVF cells isolated from adipose tissue with erbium YAG laser for 2 sessions with an interval of 1 month.

Category

Treatment - Other

2

Description

Control group: Patients are treated with physiological serum with erbium YAG laser for 2 sessions with an interval of 1 month.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Skin and Stem cell Research Center of
Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Street address

No 4, Maryam Alley, South Kamraniyeh Street,
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Nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

Central University Organization, sixth floor, Vice
Chancellor for Research and Technology, corner of
Quds Street, Keshavarz Boulevard

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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

Tehran 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

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Sona Zare

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Cellular and Molecular Biology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Masoumeh Roohaninasab

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Researcher

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable