Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 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
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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 updating data

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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