Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of nanofat graft with microneedling in the clinical improvement of striae distensae

Protocol summary

Study aim
Determination of the effectiveness of nanofat grafting in comparison with microneedling in the treatment of striae distensae

Design
Phase 3, parallel group, clinical trial, with consecutive sampling, including 20 patients, single blinded, computerized randomized with permuted blocks

Settings and conduct
The study is conducted in the Imam Reza laser clinic of Shiraz University of Medical Sciences randomly with nanofat grafting in one side (one session at the beginning of study) and microneedling in the other side (3 session once monthly). The patients are assessed at the beginning of treatment, monthly visits for microneedling and 6 months after the first visit by photography and colorimetry. The investigator is blind to the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients of 18 to 60 years of age; bilateral striae distensae (alba and rubra); site on the abdomen, buttock, calves, thighs, and arms Exclusion criteria: pregnancy; lactation; body mass index ≤ 22; history of nickel hypersensitivity; history of treatment for striae in the recent one year; history of hypertrophic scar or keloid formation; active infections on the study area; severe underlying internal diseases; history of hypercoagulation states; Consumption of immunosuppressant drugs, systemic retinoids, corticosteroids, anabolic steroids in the recent 2 months; history of allergy to any ingredient of tumescent anesthetic solution; history of abdominoplasty; scar on the fat donor site; history of Cushing syndrome; polycystic ovary syndrome; body dysmorphic disorder

Intervention groups
Intervention group: Nanofat graft in the striae of one side of body one session at the beginning of study Control group: Microneedling of the striae of one side of body 3 session monthly

Main outcome variables
Clinical improvement of striae, measured by Global aesthetic improvement scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140212016557N10**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date
2022-01-22, 1400/11/02

Registrant information

Name
Mozhdeh Sepaskhah

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 712125239

Email address
sepaskhah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-10, 1400/10/20

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of nanofat graft with microneedling in the clinical improvement of striae distensae

Public title
Effect of nanofat injection in the treatment of stretch marks
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients of 18 to 60 years of age bilateral striae distensae (alba and rubra) site on the abdomen, buttock, calves, thighs, and arms
Exclusion criteria:
pregnancy lactation body mass index less than or equal to 22 history of nickel hypersensitivity history of treatment for striae in the recent one year history of hypertrophic scar or keloid formation active infections on the study area severe underlying internal diseases history of hypercoagulation states Consumption of immunosuppressant drugs, systemic retinoids, corticosteroids, and anabolic steroids in the recent 2 months history of allergy to any ingredient of tumescent anesthetic solution history of abdominoplasty scar on the fat donor site history of Cushing syndrome history of polycystic ovary syndrome body dysmorphic disorder
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
One side of the body is allocated in the nanofat grafting group and the other side in the microneedling group.
Randomization (investigator's opinion)
Randomized
Randomization description
The participants were randomized using permuted block randomization (size of each block: 4), in individual units, using random allocation software. The output of software is a table that determines the right or left side undergoes nanofat grafting.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the different treatment methods in two sides, the participants cannot be blinded. Principle investigator, and care provider physician are also aware of the the side undergoing nanofat grafting. But, outcome assessors are not aware of the side undergoing nanofat grafting in each patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand St., Shiraz. Iran
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2021-12-20, 1400/09/29
Ethics committee reference number
IR.SUMS.MED.REC.1400.501

Health conditions studied

1

Description of health condition studied
Striae distensae
ICD-10 code
L90.6
ICD-10 code description
Striae atrophicae

Primary outcomes

1

Description
Clinical improvement of striae
Timepoint
The patients will be assessed in 3 monthly visits for microneedling, and 6 months after the first visit.
Method of measurement
Global aesthetic improvement scale, measured as: Grade 0: Worsening of lesions; Grade 1: No change (< 25% improvement); Grade 2: Improved (25-50% improvement); Grade 3: Much improved (51-75% improvement); Grade 4: Very much improved (76-100% improvement)

Secondary outcomes

1

Description
Striae size reduction
Timepoint
3 monthly visits for microneedling, and 6 months after the first visit
Method of measurement
Percentage of striae width reduction

2

Description
Striae color
Timepoint
At the beginning of treatment, 3 monthly visits for microneedling, and 6 months after the first visit
Method of measurement
Pigment index is measured by colorimetric device

3

Description
Dermoscopic features of striae
Timepoint
At the beginning of treatment, 3 monthly visits for microneedling, and 6 months after the first visit
Method of measurement
Dermatoscopic features like color, vascularity, width, and texture of striae

4

Description
Patient satisfaction
Timepoint
At the end of treatment
Method of measurement
A 5-point scale. 4: Extremely satisfied, 3:Very satisfied, 2: satisfied, 1: Slightly satisfied, 0: Not satisfied

5

Description
Pain during treatment
Timepoint
At the 3 sessions of monthly treatment
Method of measurement
Pain illustrated numerical rating scale

Intervention groups

1

Description
Intervention group: Nanofat grafting in the striae of one side of the body (one session at the beginning of study)
Category
Treatment - Surgery

2

Description
Control group: microneedling in striae of one side of the body (3 session monthly)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Laser clinic, Imam Reza clinic
Full name of responsible person
Mozhdeh Sepaskhah
Street address
Laser clinic, Imam Reza clinic, Namazi Sq.
City
Shiraz
Province
Fars
Postal code
7134814734
Phone
+98 71 3212 7001
Email
sepaskhah@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memar zade
Street address
Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
22872
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mozhdeh Sepaskhah
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 5239
Fax
+98 71 3231 9049
Email
sepaskhah@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mozhdeh Sepaskhah
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3212 5239
Fax
+98 71 3231 9049
Email
sepaskhah@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mozhdeh Sepaskhah
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
Street address
Shiraz University of Medical Sciences, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 5239
Fax
+98 71 3231 9049
Email
sepaskhah@sums.ac.ir
Web page address

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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available