Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of autologous fat grafting in the face of patients with systemic sclerosis

Protocol summary

Study aim

Evaluation of mouth opening capacity of patients after fat transfer Evaluation of mouth handicap in systemic sclerosis (MHISS) score after fat transfer Evaluation of Skin sclerosis based on Rodnan skin score on face after fat transfer Evaluation of Skin elasticity after fat transfer

Design

Clinical trial , before-after

Settings and conduct

Autologous fat grafting procedure: Given the easier access to a sufficient amount of adipose tissue, the trochanteric, the flank, the periumbilical or the buttock area were chosen as the donor sites. The entry points for the infiltration cannula were anesthetized with 1ml pure lidocaine with a 30 gage needle. Then 500 ml of Tumescent solution, containing normal saline, 25 ml of lidocaine 2% and .5 ml of epinephrine 1:1000 was infiltrated in the selected donor area with 1.5 mm cannula. After twenty minutes, adipose tissue was harvested using a 3 mm blunt tipped cannula which was connected with a luer-lock 10 ml syringe, using low vacuum pressure. The collected adipose tissue in each 10 ml syringe left to sediment by gravity for 10 minutes. Oil and blood excess eliminated and the remaining fat was transferred into the 1 ml syringe and was directly injected into the face using disposable 18-gage cannulas. Subcutaneous injections were performed into different locations: perioral, upper lip,and lower lip, mouth corners, buccal, malar and periorbital regions. All patients were evaluated at baseline and 3 months after the procedure.

Participants/Inclusion and exclusion criteria

Patients fulfilling the “American college of Rheumatology” criteria for systemic sclerosis with facial involvement Exclusion criteria were as follow: 1)Pregnant or breastfeeding; 2)Patients with diffuse skin sclerosis who had insufficient fat harvesting; 3)Recently diagnosed patients with SSc who had not clear face and oral involvement; 4) Patients with history of neoplasia in the last 5 years; 5) Who were taking prednisolone more than 10mg/d.

Intervention groups

Patients fulfilling the criteria for systemic sclerosis with facial involvement

Main outcome variables

Increase in mouth opening capacity after fat transfer Decrease in mouth handicap in systemic sclerosis (MHISS) score after fat transfer Decrease in skin sclerosis based on Rodnan skin score on face after fat transfer Increase in skin elasticity after fat transfer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180209038677N1**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Nikoo Mozafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2274 1507

Email address

n.mozafari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01
Expected recruitment end date
2017-08-23, 1396/06/01
Actual recruitment start date
2017-03-21, 1396/01/01
Actual recruitment end date
2017-08-23, 1396/06/01
Trial completion date
empty

Scientific title
Evaluation of the efficacy of autologous fat grafting in the face of patients with systemic sclerosis

Public title
Autologus fat grafting for scleroderma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients fulfilling the “American college of Rheumatology” criteria for systemicsclerosis with facial involvement
Exclusion criteria:
Pregnant or breastfeeding; Patients with diffuse skin sclerosis who had insufficient fat harvesting; Recently diagnosed patients with SSc who had not clear face and oral involvement; Patients with history of neoplasia in the last 5 years; Who were taking prednisolone more than 10mg/d.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **16**
Actual sample size reached: **16**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Shahid Beheshti University of Medical Sciences
Street address
School of Medicine, Koodakyar St. Danshjoo Blv, Velenjak, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2017-03-08, 1395/12/18
Ethics committee reference number
IR.Sbmu.src.rec.1395.45

Health conditions studied

1

Description of health condition studied
Systemic scleroderma
ICD-10 code
M34
ICD-10 code description
Systemic sclerosis [scleroderma]

Primary outcomes

1

Description
Mouth opening capacity: maximal distance in cm between the upper and lower incisors.
Timepoint
Baseline and 3 months after procedure
Method of measurement
Ruler

2

Description
Mouth handicap in systemic sclerosis (MHISS) scale
Timepoint
Baseline and 3 months after procedure
Method of measurement
12-item questionnaire of MHISS

3

Description
Skin sclerosis score
Timepoint
At baseline and 3 months after procedure
Method of measurement
Rodnan skin score

4

Description
Skin elasticity
Timepoint
At baseline and 3 months after procedure
Method of measurement
Reviscometer

Secondary outcomes

1

Description
Aesthetic effect
Timepoint
At baseline and 3 months after procedure
Method of measurement
Photography before and after procedure

Intervention groups

1

Description
Intervention group: autologous fat transfer
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman-e-Hakim Hospital
Full name of responsible person
Niloofar Noubari
Street address
Makhsus St. Qazvin St. Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1333631151
Phone
+98 21 5541 9005
Email
niloofar.nobari@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parviz Toosi
Street address
Skin research center, Shohada-e-Tajrish hospital,Shahrdari st, Tajrish Sq., Tehran, Iran
City
تهران
Province
Tehran
Postal code
1989934148
Phone
+98 21 2274 1507
Email
src@sbmu.ac.ir
Web page address
http://src.sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nikoo Mozafari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Skin research center, Shohada-e-Tajrish hospital, Tajrish square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2274 1507
Email
Nikoo_md@yahoo.com
Web page address
http://src.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nikoo Mozafari

Position
Assistant proffessore

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Skin research center,Shohada-e-Tajrish hospital, Tajrish square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 1507

Email
Nikoo_md@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nikoo Mozafari

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
Skin research center, Shohada-e-Tajrish Hospital, Tajrish sq, Tehran, Iran.

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 2274 1507

Email
Nikoo_md@yahoo.com

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
Yes - There is 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
Patients demographic data results of project

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
Only available for people working in academic institutions

Under which criteria data/document could be used
Any analysis will be allowed

From where data/document is obtainable
Nikoo_md@yahoo.com

What processes are involved for a request to access data/document
The applicant can send Email to me, the requested information will be sent to them immediately

Comments