

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Autologous 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.

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget 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. Danshjoor 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 (MHSS) scale

Timepoint

Baseline and 3 months after procedure

Method of measurement

12-item questionnaire of MHSS

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.

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1333631151

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niloofar.noubari@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

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Phone

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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

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Skin research center, Shohada-e-Tajrish hospital,
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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

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Other areas of specialty/work

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Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nikoo Mozafari

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Email

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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

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