

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of survival in serial autologous fat transfer between freezed and fresh fat in face rejuvenation

Protocol summary

Study aim

Determination and comparison of shelf-life in serial transfer of autologous fat graft stored at freezing temperature and fresh fat in facial rejuvenation

Design

In this study, a single-blind randomized phase 3 clinical trial is performed in the form of parental groups. Sixty patients were divided into two groups by computer randomization.

Settings and conduct

This study was carried out in 2020 at Alzahra Hospital in Isfahan. This study was conducted as a single-blind study and the person who evaluate of the outcome of the intervention is unaware about the kind of intervention.

Participants/Inclusion and exclusion criteria

In this study, patients who are candidates for facial fat injection for the purpose of facial rejuvenation, aged 18 to 69 years, were enrolled. Patients with a history of allergies are also excluded from the study.

Intervention groups

In this study, 60 patients who were candidates for facial fat injection were divided into two groups of 30 each. In the first group, fat tissue samples are taken from the inner part of the thigh or abdomen and frozen and used repeatedly. In the second group, at each injection, fresh fat samples are taken from the patient and injected into the facial tissue.

Main outcome variables

Wrinkle-removing of nasolabial area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N43**

Registration date: **2020-03-16, 1398/12/26**

Registration timing: **prospective**

Last update: **2020-03-16, 1398/12/26**

Update count: **0**

Registration date

2020-03-16, 1398/12/26

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-09-17, 1399/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of survival in serial autologous fat transfer between freezed and fresh fat in face rejuvenation

Public title

Comparison of shelf life of fresh and frozen injections of facial rejuvenation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for fat injection for facial rejuvenation
Patient's consent to participate in the study
Exclusion criteria:
History of any type of allergy

Age
From **18 years** old to **69 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of patients in two groups is done by Random Allocation Software. The total sample size is then entered into the software and then the number of groups is determined. The output of the software is a list containing numbers from one to 60 that are distributed randomly into two groups. According to the list, Patients are distributed into two groups according to the time of referral in order to reach the required sample size in each group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Because of the frequency of adipose tissue differentiation between the two groups, it is not possible to blind the patient. Liposuction and injection are performed by the researcher, but the outcome of treatment and evaluation of the effects of the injection are performed by other plastic surgeon who That is unaware of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Alzahra hospital, Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8434193474

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.MUI.REC..1398.288

Health conditions studied

1

Description of health condition studied

Facial wrinkles

ICD-10 code

R23.4

ICD-10 code description

changes in skin texture

Primary outcomes

1

Description

Facial Wrinkles

Timepoint

Every 3 months

Method of measurement

Modified Fitzpatrick Wrinkle Scale

2

Description

Survival Fat injected

Timepoint

every 3 months

Method of measurement

Physical Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group,during tree time of visit, about 10 ml of fresh fat is aspirated from the inner thigh and after purification, 3 ml is injected on both sides of the nasolabial folds. The frequency of fat injections will be three times with 3 weeks interval.

Category

Treatment - Surgery

2

Description

Intervention group 2: In this group, about 30 ml of fat is aspirated from the inner part of the thigh and after purification, 3 ml is injected on both sides of the

nasolabial folds. The residual fat is freeze at -18 ° C and is injected at similar volume for the two next injections with interval of three weeks

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Enayatollah Yadollahi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayesh Haghjoo

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Vice chancellor for research and technology, Isfahan University of Medical Sciences, Hezar Jerib street.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahmoud Omranifard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

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Full name of responsible person

Ali Mehrabi

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Statistical Consultant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The project is owned by the government agency and its
information is not 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