

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of fat injection with and without stromal vascular fraction in the treatment of nasolabial and cheek wrinkles

Protocol summary

Study aim

Comparison of fat injection and fat with stromal vascular fraction injection in the treatment of nasolabial and cheek wrinkles

Design

Clinical trial with control group, with factorial design, one side blinded, randomized, phase 3 on 20 patients. Even and odd numbers used for randomization.

Settings and conduct

20 patients referred to the outpatient clinic of Sinai hospital with medium to deep nasolabial and cheek wrinkles will be randomly selected and randomly divided into two groups of 15 patients. One group will be with fat injections and the other group will be injected with svf and fat injections obtained from the patient. After the injection, the patient will be monitored for 3, 6 and 12 months for the severity of wrinkles, complications (any reaction at the injection site, erythema, bruising, papules, nodules, etc.) and the stability of the effects of the injection. .

Participants/Inclusion and exclusion criteria

Age older than 65 years old; patient satisfaction, and moderate to deep nasolabial wrinkles. Exclusion criteria: diabetes; allergy to svf; hematologic and coagulation problems; smoking; pregnancy; aspirin use; and immune system defects.

Intervention groups

Patients receive 5 ml of pure fat and 5 ml of svf using needle number 27 within 7 minutes. Control group: patients receive 5 ml of pure fat using needle number 27 within 7 minutes.

Main outcome variables

The severity of nasolabial and cheek wrinkles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140705018373N4**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **prospective**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Mohamad Reza Ranjkesh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 116 5061

Email address

ranjkeshm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-05, 1399/04/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

2020-09-05, 1399/06/15

Actual recruitment end date

2020-11-05, 1399/08/15

Trial completion date

2020-12-05, 1399/09/15

Scientific title

Comparison of fat injection with and without stromal vascular fraction in the treatment of nasolabial and cheek wrinkles

Public title

Effect of fat injection with and without SVF in the treatment of facial wrinkles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age under 65 years old Patients satisfaction Middle to deep nasolabial wrinkles

Exclusion criteria:

Diabetes melitus Patients with hematologic and coagulation problems Smoking Pregnancy Use of Aspirin Patients with defective immune system

Age

To 65 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 20

Actual sample size reached: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using the patient file number and using even and odd numbers. The criterion will be the last digit of the patient's file number and the number zero will be considered even. Evens will be considered as a study group and odd numbers as a control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be blinded for the type of solution injected.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Sina hospital, between Hafez and Shahid-Montazeri square, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Approval date

2020-07-05, 1399/04/15

Ethics committee reference number

TBZMED.REC.1399.218

Health conditions studied

1

Description of health condition studied

Nasolabial and cheek wrinkles

ICD-10 code

Other and

ICD-10 code description

R23.8

Primary outcomes

1

Description

Nasolabial and cheek wrinkle severity

Timepoint

Before injection, 3, 6 and 12 months after injection

Method of measurement

Wrinkle Severity Rating Scale

Secondary outcomes

1

Description

The degree of tissue healing and homogeneity of facial skin

Timepoint

Before injection, 3, 6 and 12 months after injection

Method of measurement

Skin Homogeneity and Texture Scale

Intervention groups

1

Description

Intervention group: Patients receive 5 ml of pure fat and 5 ml of svf (stromal vascular fraction) using needle number 27 within 7 minutes.

Category

Treatment - Drugs

2

Description

Control group: Patients receive 10 ml of pure fat using needle number 27 within 7 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Mohammadreza Ranjkesh

Street address

Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ata Mahmoudpour

Street address

Vice chancellor for Research ,Faculty of Medicine,
Golgash Street

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3385 1117

Email

amahmoodpoor@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Tabriz 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

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Leila Asadi

Position

Dermatology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Sina hospital, between Hafez and Shahid-Montazeri square, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

Leilaasadi463@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Ranjkesh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Ranjkesh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

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

There is a plan to make this available

When the data will become available and for how long

Study data is categorized and coded with no identifiable individuals. When the data will become available and for how long

To whom data/document is available

Access to study data after publication of the result is available in the journal. To whom data/document is available

Under which criteria data/document could be used

Anyone interested in using the data can access the study data. Under which criteria data/document could be used

From where data/document is obtainable

Study data can be used for comparison with other results. From where data/document is obtainable

What processes are involved for a request to access data/document

Refer to the study's scientific or public accountability person for data.

Comments

The use request will be emailed to the scientific or public accountability person.