

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effects and complications of classic and nanofat fat injections in reducing wrinkles, dimples and dark circles around the eyes

Protocol summary

Study aim

This study aimed to compare the effects and side effects of classic and nano fat injections in reducing wrinkles, dimples, and darkness around the eyes.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients.

Settings and conduct

This study will be conducted at Sina Hospital in Tabriz. The study is a double-blind study in which the dermatologist evaluating the treatment outcome as well as the person analyzing the data do not know about the intervention groups (injected solution).

Participants/Inclusion and exclusion criteria

The criteria for entering the study include darkness, dimples, and wrinkles around the eyes, lack of response to topical treatments, and consent to participate. Patients with cardiovascular diseases, coagulopathy, or the use of anticoagulants and puffiness around the eyes will be excluded.

Intervention groups

Patients will be randomly divided into intervention and control groups. In the intervention group, 20 ccs of fat will be injected, 10 to 15 cc in the form of micrograft (2 to 3 cc in each eye) and 4 to 5 cc in the form of nano fat (1 to 2 cc in each eye) and the injection will be separately. In the control group, 15 ccs will be injected as a micrograft and 2 to 3 cc for each eye.

Main outcome variables

Severity of wrinkles around the eyes; Severity of the dimples around the eyes; Severity of dark circles under the eyes; Possible side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140705018373N6**

Registration date: **2022-12-24, 1401/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-24, 1401/10/03**

Update count: **0**

Registration date

2022-12-24, 1401/10/03

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

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects and complications of classic and nanofat fat injections in reducing wrinkles, dimples and dark circles around the eyes

Public title

Effects and complications of classic and nanofat fat injections in reducing wrinkles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Visible darkness, dimples and wrinkles around the eyes
Failure to respond to topical treatments
Consent to participate in the study

Exclusion criteria:

Cardiovascular diseases
Coagulation diseases or use of anticoagulants
Puffiness around the eyes

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using patient file numbers and using even or odd numbers. The criterion is the last digit of the number and the number zero will be considered even. Even numbers will be considered as intervention group and odd numbers as control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The dermatologist evaluating the final effect of the intervention and possible complications as well as the person analyzing the data will be blinded to the type of intervention.

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

2022-11-21, 1401/08/30

Ethics committee reference number

IR.TBZMED.REC.1401.770

Health conditions studied

1

Description of health condition studied

Wrinkles around the eyes

ICD-10 code

L98

ICD-10 code description

Other disorders of skin and subcutaneous tissue, not elsewhere classified

2

Description of health condition studied

Dimples around the eyes

ICD-10 code

L98

ICD-10 code description

Other disorders of skin and subcutaneous tissue, not elsewhere classified

3

Description of health condition studied

Dark circles under the eyes

ICD-10 code

L98

ICD-10 code description

Other disorders of skin and subcutaneous tissue, not elsewhere classified

Primary outcomes

1

Description

Severity of wrinkles around the eyes

Timepoint

First week, second week, third week and fourth week after injection

Method of measurement

Using the visual analog scale, poor: less than 25% recovery, moderate: between 26% and 50% recovery, good: between 51 and 75% recovery, excellent: between 76 and 90% recovery and perfect: between 91 and 100% recovery; will be evaluated.

2

Description

Severity of dimples around the eyes

Timepoint

First week, second week, third week and fourth week after injection

Method of measurement

Using the visual analog scale, poor: less than 25% recovery, moderate: between 26% and 50% recovery, good: between 51 and 75% recovery, excellent: between 76 and 90% recovery and perfect: between 91 and 100% recovery; will be evaluated.

3

Description

Severity of dark circles around the eyes

Timepoint

First week, second week, third week and fourth week after injection

Method of measurement

Using the visual analog scale, poor: less than 25% recovery, moderate: between 26% and 50% recovery, good: between 51 and 75% recovery, excellent: between 76 and 90% recovery and perfect: between 91 and 100% recovery; will be evaluated.

4

Description

Complications after injection

Timepoint

First week, second week, third week and fourth week after injection

Method of measurement

It is based on clinical examination and includes evaluation of allergy, hematoma, infection, numbness or change in sensation, and scar.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 cc of fat will be injected, 10 to 15 cc in the form of micrograft (2 to 3 cc for each eye) and 4 to 5 cc in the form of nanofat (1 to 2 cc for each eye).

Category

Treatment - Other

2

Description

Control group: 15 cc will be injected as a micrograft (2 to 3 cc for each eye).

Category

Treatment - Other

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.

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. Mohammadreza Ranjkesh

Street address

Sina hospital, Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

empty

Country of origin

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. Mohammadreza Ranjkesh

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Sina hospital, Azadi Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

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.

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.

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

No - There is not 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

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

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

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

The request will be sent by email to person responsible for scientific or public inquiries.

Comments