

# 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**