Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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. Mohmmadreza Ranjkesh
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Sina hospital, Azadi Ave.
City
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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. Mohmmadreza Ranjkesh
Position
Associate Professor
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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