

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigation the effect of injection of nanofat for correction of fine facial wrinkles

#### Protocol summary

##### Study aim

Determining the effectiveness of injection of nanofat for correction of fine facial wrinkles

##### Design

This study is a randomized clinical trial, 15 patients who will be referred to dermatology clinic of faghihi hospital will be enrolled randomly. As far as the methodology is concerned, due to lack of similar studies, considering statistician, investigating at least 15 patients would be sufficient. The fat from abdomen will be harvested from these patient abdomen under local anesthesia, the fat will be processed to nanofat and injected intradermally in facial wrinkles. The photo of patients will be taken prior and 7 month after the injection. Volume, depth and area of wrinkles will be measured with visioface 1000D, and data will be analyzed with paired t-test. This study doesn't have control group.

##### Settings and conduct

This study will be done in dermatology clinic of shiraz faghihi hospital. The fat will be harvested from the patient's abdomen and processed to nanofat and injected intradermally into the facial wrinkles. Photo will be taken before and 7 month after the procedure and volume, depth and area of the wrinkles will be evaluated by the visioface 1000D. All the patients will sign the informed consent.

##### Participants/Inclusion and exclusion criteria

Patients between 30-65 years old who will be referred to dermatology clinic of shiraz faghihi hospita, with fine facial wrinkles will be enrolled in this study randomly. Patients should not have history of facial trauma recent filler injection, recent botox injection, co-morbidities, operation for correction of facial wrinkle.

##### Intervention groups

Patients with fine facial wrinkles in forehead area, the fat will be aspirated from their abdomen in one session, processed to nanofat and injected in their wrinkles.

##### Main outcome variables

Area of facial wrinkles, volume of facial wrinkles, depth of

facial wrinkles

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210303050559N1**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **retrospective**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

##### Registration date

2022-12-03, 1401/09/12

##### Registrant information

##### Name

farzane akbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3639 2561

##### Email address

farzane.akbarii@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-10, 1399/12/20

##### Expected recruitment end date

2021-03-18, 1399/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigation the effect of injection of nanofat for correction of fine facial wrinkles

### Public title

Nanofat in fine facial wrinkles

### Purpose

Other

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having fine facial wrinkles in forehead area

#### Exclusion criteria:

Having history of facial trauma Co-morbidities Botox injection 6 months before and 7 months after procedure

Previous operation for facial wrinkles Filler injection for the facial wrinkles

### Age

From **30 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **15**

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

University of medical science, zand street, shiraz

##### City

shiraz

##### Province

Fars

##### Postal code

7134845794

#### Approval date

2019-04-22, 1398/02/02

### Ethics committee reference number

IR.SUMS.MED.REC.1398.089

## Health conditions studied

### 1

#### Description of health condition studied

Facial wrinkles

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Depth of facial wrinkles

#### Timepoint

Before fat injection and 7 month later

#### Method of measurement

Using a device, visioface 1000D (ck electronic, manufactured in germany)

### 2

#### Description

Volume of facial wrinkle

#### Timepoint

Before fat injection and 7 month later

#### Method of measurement

Using a device, visioface 1000D (ck electronic, manufactured in germany)

### 3

#### Description

Area of facial wrinkle

#### Timepoint

Before fat injection and 7 month later

#### Method of measurement

Using a device, visioface 1000D (ck electronic, manufactured in germany)

## Secondary outcomes

### 1

#### Description

Decreasing the depth of facial wrinkle

#### Timepoint

Before the fat injection and 7 month later

#### Method of measurement

Using a device, visioface 1000D ( ck electronic, manufactured in germany)

### 2

#### Description

Decreasing the volume of facial wrinkle

#### Timepoint

Before the fat injection and 7 month later

### Method of measurement

Using a device, visioface 1000D ( ck electronic, manufactured in germany)

### 3

#### Description

Decreasing the area of facial wrinkle

#### Timepoint

Before the fat injection and 7 month later

#### Method of measurement

Using a device, visioface 1000D ( ck electronic, manufactured in germany)

## Intervention groups

### 1

#### Description

Intervention group: The effect of nano-fat injection in correcting fine facial wrinkles in patients over 40 years old with facial wrinkles referred to the skin department of Faghihi Hospital in Shiraz, any area with excess fat deposits is selected as a donor site. Surface injection of 2% lidocaine is performed with a 27G fine needle at the cannula entry points. Any area with excess fat deposits is selected as a donor site. Surface injection of 2% lidocaine is performed with a 27G fine needle at the cannula entry points. The infiltration cannula is a 3 mm diameter blunt-tipped device with many side openings attached to a 10 or 20 cc syringe. Fat (about 10 cc) after infiltration, mostly from the lower abdomen (or thigh) was removed with about 250 cc of swelling solution containing 1 mg of epinephrine 1:1000, 1000 cc of 0.9% normal saline and 25 ml of 2% lidocaine. will be The harvested fat is filtered through a sterile 0.5 mm pore size filter and then transferred between two 10 cc syringes connected to each other by a female-to-female luer-lok connector. After about 30 passes, the fat turns into an emulsion. At the end of the fragmentation process, the fat is liquefied and easily passes through the sharp needle (27G). The patient's face is anesthetized with topical lidocaine, and the processed fat is injected into the fine wrinkles. Patients are evaluated before, immediately after and 3 months after treatment. In each visit, we take pictures from the front, left and right with Visioface 1000D (Electronic CK, made in Germany). This device has the ability to measure volume, area and depth as three specified parameters of wrinkles that are quantitatively compared before and after treatment. Also, the side effects of fat grafting, such as erythema, edema, ecchymosis, and infection, will be explained to patients.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Shiraz Faghihi hospital, dermatology clinic

#### Full name of responsible person

Farzaneh akbari

#### Street address

Faghihi hospital, zand street, shiraz

#### City

Shiraz

#### Province

Fars

#### Postal code

7134846114

#### Phone

+98 71 3231 9049

#### Fax

+98 71 3231 9049

#### Email

Farzane.akbarii@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Abbas rezaeian zade

##### Street address

Central office of medical university, zand street, shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

##### Phone

+98 71 3230 5410

##### Fax

+98 71 3230 5410

##### Email

Vcrdep@sums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh akbari

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology clinic, Faghihi hospital, zand street,  
shiraz

**City**

Shiraz

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**Postal code**

7134846114

**Phone**

+98 71 3231 9049

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Farzane.akbarii@gmail.com

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**Email**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh akbari

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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**Postal code**

7134846114

**Phone**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzane Akbari

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Dermatology clinic, faghihi hospital, zand street,  
shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7134846114

**Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available