

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**A comparative study of the durability of fat injection alone with respect to fat injection along with the injection of Hyaluronic Acid gel(Profilo) in the cheeks of patients referred to Razi Hospital in the years 1399-1400**

### Protocol summary

#### Study aim

A comparative evaluation of the durability of fat injection alone with respect to fat injection with Hyaluronic acid gel (profilo) according to the criteria, GAIS / patient, GAIS / DR

#### Design

A clinical trial study with an intervention group and a parallel control group Randomization is block and one-sided blind.

#### Settings and conduct

This study is performed in Razi Dermatology Hospital. Patients were selected according to the inclusion criteria and if they did not meet the exclusion criteria, in the selected sample size and after initial scoring based on the Wrinkle Severity Rating Scale (WSRS) and after taking photography pictures randomly by block method, they will be placed in two groups of intervention and control. Outcome assessment is performed 1 month and 6 months after fat injection

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 70 years. (Wrinkle assessment) Between 2-4. Signature informed consent. Exclusion criteria: Candidate for surgery. History of sensitivity to Tumescant solution. History of allergies to hyaluronic acid gels and other gels. History of allergies to injection equipment. Aspirin use. Taking immunosuppressive drugs. Having certain diseases or uncontrolled underlying diseases (such as neuromuscular diseases). In pregnant women. Patients should not have a history of filler or fat injections in the past 12 months

#### Intervention groups

Intervention: After fat injection in the face, injection of 2 cc hyaluronic acid gel (profilo) in the face in 2 consecutive sessions 2 weeks apart. Control: Only inject fat into the face

#### Main outcome variables

Scoring based on GAIS / Dr and GAIS / Patient forms

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210519051343N1**

Registration date: **2021-11-24, 1400/09/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-24, 1400/09/03**

Update count: **0**

#### Registration date

2021-11-24, 1400/09/03

#### Registrant information

##### Name

Marwa Akhdar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4445 0004

##### Email address

marwaakhdar@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-11-21, 1400/08/30

#### Expected recruitment end date

2021-12-21, 1400/09/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

## Scientific title

A comparative study of the durability of fat injection alone with respect to fat injection along with the injection of Hyaluronic Acid gel(Profhilo) in the cheeks of patients referred to Razi Hospital in the years 1399-1400

## Public title

Evaluation of durability of fat injection with Hyaluronic acid gel (Profhilo)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

age between 18 and 70 years old score of Wrinkle Severity Rating Scale between 2-4 patients who don't want to do surgical procedures signing an inform consent

### Exclusion criteria:

Candidate for cosmetic facial surgery pregnancy and lactation neuromuscular disease uncontrolled systemic disease infection, scar, or abnormality at the site of injection a history of filler or fat injection in the past 12 months patients under treatment with immunosuppressive drugs, aspirin, narcotics, antidepressants, and corticosteroids history of adverse reactions to hyaluronic acid gel and other gels history of adverse reaction to tumescent solution adverse reactions to injection instruments( needle and cannula) facial asymmetry

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **10**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Excel software will be used for randomization. In one column, 5 letters A and 5 letters B are recorded, and in the adjacent column, 10 random numbers are created with the Rand () command. The sequence of both columns is then sorted from large to small based on a column of random numbers. The sequence obtained for the letters A and B will be the criteria for entering the two groups of intervention and control.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

After doing the procedures and taking photographs, the other two dermatologists will separately look at the photographs taken at each visit and will give a score based on the photographs.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

vahdat islami square-vahdat islami street-razi hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

#### Approval date

2020-10-12, 1399/07/21

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.606

## Health conditions studied

### 1

#### Description of health condition studied

autologous fat transplant with and without Profhilo hyaluronic acid gel

#### ICD-10 code

Z41.1

#### ICD-10 code description

Encounter for cosmetic surgery

## Primary outcomes

### 1

#### Description

specialist's score based on GAIS-doctor score

#### Timepoint

baseline-1 month after -6 months after

#### Method of measurement

Measurement based on the score given by the non-executive physician based on GAIS-doctor score which includes 7 scores:1- very much improved.2-: much improved.3-: improved.4-: no change.5-worse.6- much worse.7- very much worse.

## Secondary outcomes

### 1

#### Description

wrinkle severity

#### Timepoint

baseline-1 month after- 6 months after

#### Method of measurement

measurement is done according to the Wrinkle Severity Rating Scale (WSRS) scoring system which includes 5 scores:0- Absent.1- Slight wrinkles.2-Quite evident wrinkles.3-Evident wrinkles.4-Marked wrinkles.5-Very marked wrinkles.

## Intervention groups

### 1

#### Description

Intervention group: The group that undergoes hyaluronic acid gel injection after fat injection - selected fat donor sites of the outer thigh. Aspiration is done with a cannula to collect the fat pieces. Then the obtained liquid is centrifuged and then the fat is separated as a yellow and smooth layer and this layer of fat is injected with a 2 ml syringe and canola number 14 can be used. About 30 ml of total fat is injected into the cheeks on both sides. After injection, antibiotics and anti-inflammatory drugs are prescribed. Hyaluronic Acid gel (prophilo) with a dose of 2 ml per session (1 ml on each side of the cheek) is then injected during 2 sessions at intervals 2 and 4 weeks after fat injection. The prophilo injection is done according to the 5 point technique.

#### Category

Treatment - Other

### 2

#### Description

Control group: In this group, patients are injected only with fat, which is extracted from the outer part of the thigh and centrifuged, and about 30 ml is injected in each cheek on each side of the patient's face. Patients in this group are not injected with prophilo gel.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital-Tehran University of Medical Sciences

##### Full name of responsible person

vahideh lajevardi

##### Street address

Vahdat Islami square- Vahdat Islami street- razi hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1199663911

##### Phone

+98 21 5563 0174

##### Fax

+98 21 5563 4461

##### Email

razihospital@sina.tums.ac.ir

##### Web page address

<https://razihos.tums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraian

##### Street address

6th floor, central Medical University Building,Qods street,Keshavarz boulevard

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3698

##### Email

research@tums.ac.ir

##### Web page address

<https://www.tums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran University of Medical Sciences

#### Proportion provided by this source

20

#### 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

### 2

#### Sponsor

##### Name of organization / entity

IBSA pharmeceutics

##### Full name of responsible person

Armin Ghaedi

##### Street address

Unit no.2-2nd floor-plaque no 60- east maryam street-Elahie

##### City

Tehran

##### Province

Tehran

##### Postal code

1964966335

**Phone**

+98 21 2204 4991

**Email**

info@paeezanco.com

**Web page address**

<http://paeezanco.com/home>

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

Paeezan Tejarat Mehr

**Proportion provided by this source**

80

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Houshang Ehsani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Razi hospital- razi alley-vahdat esmali square

**City**

Tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5563 0223

**Email**

ehsani@sina.tums.ac.ir

**Web page address**

<https://razihos.tums.ac.ir>

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Amir Houshang Ehsani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Razi hospital-razi alley- vahdat eslami square

**City**

tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5563 0223

**Email**

ehsani@tums.ac.ir

**Web page address**

<https://razihos.tums.ac.ir>

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Marwa Akhdar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Razi hospital-razi alley-vahdat eslami street

**City**

Tehran

**Province**

Tehran

**Postal code**

1199663911

**Phone**

+98 21 5561 8989

**Email**

marwaakhdar@razi.tums.ac.ir

**Web page address**

<https://razihos.tums.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**

All data will be accessible for academic researchers after covering the identities

**When the data will become available and for how long**

after being published by the journal, all data will be accessible forever

**To whom data/document is available**

for all academic researchers in the field of medicine and

pharmacology

**Under which criteria data/document could be used**

Just for using in research fields and respecting the original researchers in any referencing

**From where data/document is obtainable**

emailing the main researcher via this email: marwaakhdar@live.com

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

just an email containing information about the academic position of the researchers and their responsibilities

**Comments**