Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim

A comparative evaluation of the durability of fat injection alone with respect to fat injection with Hyaluronic acid gel (profhilo) 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 Tumescent 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 (profhilo) 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 (profhilo) 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 profhilo 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 profhilo 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
ehsanih@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
ehsanih@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 hospiral-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