

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluating the effectiveness of subcision in combination with Prophilos in comparison with subcision filler injection alone on acne scar among patients treated at the dermatology clinic

Protocol summary

Study aim

To determine the effect of Prophilos filler injection on atrophic acne scars in addition to subcision and comparing this to subcision alone.

Design

A clinical trial using both arm of case and control (each patient will be himself control) with 12 patient divided into two parallel groups by block randomization and blindness (the analyzing person).

Settings and conduct

the study will be ran in the Razi hospital, dermatologic operating room. the image analyser physician and the sonographer are single side blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adults aging 18-40; presence of atrophic acne scar bilaterally; to be candida of subcision procedure; desire for participation after informed consent; no previous surgical procedure in the filed during last 3 months Exclusion criteria: previous filler injection at the site of procedure; hypercoagulability disorder; any infection at the site of procedure; allergy to hyaluronic acid products; breast feeding and pregnancy; isotretinoin consumption during last 6 months

Intervention groups

The intervention side of the face will undergo subcision and Prophilos injection subsequently and the control side of the face will only receive subcision. All of these procedures will be repeated after 1 month.

Main outcome variables

Improvement grading of the lesions according to a dermatologist opinion; Improvement grading of lesions according to ultrasonic evaluation; Improvement scaling according to the patient opinion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201210049671N1**
Registration date: **2021-04-08, 1400/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-08, 1400/01/19**

Update count: **0**

Registration date

2021-04-08, 1400/01/19

Registrant information

Name

Mani Dastgheib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8612 7032

Email address

mani.dastgheib@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-04, 1399/12/14

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of subcision in combination

with Profilla in comparison with subcision filler injection alone on acne scar among patients treated at the dermatology clinic

Public title

Effectiveness of Profilla on Acne scar.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aging between 18-40 Presence of bilateral atrophic acne scar Being a potential candida for subcision procedure Informed consent and patient agreement for participation No previous procedure in last 3 months

Exclusion criteria:

Previous filler injection in the intervening site Coagulation disorder Autoimmune diseases Infection at the site Allergy to hyaluronic acid products Pregnancy and breast feeding Isotretinoin consumption during last 6 months

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each side of the faces will be considered in the case or control groups.

Randomization (investigator's opinion)

Randomized

Randomization description

the face of each individual will be designated to two sides of right and left and for a different procedure in each side. Any procedure will be done by block randomization using a software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients and the treating physician are aware about the side of procedures. But informations about the specific procedures on each side of the face will be withheld from the sonographer and final image analysers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee for Ethics in Biomedical Research

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.293

Health conditions studied

1

Description of health condition studied

Atrophic acne scar

ICD-10 code

L70

ICD-10 code description

Acne

Primary outcomes

1

Description

Acne scar depth

Timepoint

At baseline and after 3 months

Method of measurement

Skin ultrasonography

2

Description

Total acne scar severity

Timepoint

At the base of study and after 3 months

Method of measurement

Photographic image analysis by dermatologist

3

Description

Acne severity based on self-assessment scoring

Timepoint

At the base of study and then after 3 months

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The randomized site of the face will undergo subcision and intradermal Profiller injection, and will be repeated after 1 month.

Category

Treatment - Other

2

Description

Control group: The opposite side will undergo subcision only and will be repeated after 1 month.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Vahideh Lajvardi

Street address

Vahdat Eslami street

City

Tehran

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Email

razihospital@sina.tums.ac.ir

Web page address

<http://razihos.tums.ac.ir/Home>

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

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1417653761

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Email

research@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 Farmaceutici

Full name of responsible person

Armin ghaedi

Street address

Unit no. 1, 2nd floor, plaque no. 60, East Maryam street, Elahie

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Phone

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Email

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Web page address

<http://paezanco.com/home>

Grant name

Grant code / Reference number

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

No

Title of funding source

Paezan 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

Kamran Balighi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Razi Hospital, Razi alley, Vahdat Eslami Square

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mani Dastgheib

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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City

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Fax**Email**

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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 journal publication, all data will be accessible for ever.

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 references.

From where data/document is obtainable

Calling the main researchers using this email:
mani.dastgheib@gmail.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