

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of efficacy and safety of microneedling and phenytoin cream 1% compared to microneedling in atrophic scars caused by facial acne: a double-blind randomized clinical trial

Protocol summary

Study aim

Evaluation of efficacy and safety of microneedling and phenytoin cream 1% in comparison with microneedling in atrophic scars caused by facial acne

Design

Double-blind clinical trial, randomized, phase 3 on 25 patients, randomized with sealed envelope.

Settings and conduct

This study is performed in the center of Rasoul Akram Hospital in Tehran. All participants in this study will be blind. Physicians who monitor patient outcomes and collect and analyze information are also blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with atrophic facial acne scars aged 18-45 years 2-Patients with skin type 1-4
Exclusion criteria: 1) Sensitivity to phenytoin 2) Patients who have received laser treatment in the last three months. 3) Patients with active colloidal scar or active pigmented lesion at the injection site. 4) History of malignancy or receiving chemotherapy

Intervention groups

In this study, the intervention group is patients with atrophic scar lesion. The control group is the same as the intervention group. In each patient, one side of the face receives microneedling and phenytoin cream, which is considered the intervention group, and on the opposite side of the face, only microneedling is performed, which is considered as the control group

Main outcome variables

Qualitative and quantitative severity of atrophic scars

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211108052997N1**

Registration date: **2021-12-18, 1400/09/27**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **0**

Registration date

2021-12-18, 1400/09/27

Registrant information

Name

Arezoo Pashaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 0942

Email address

Pashaei.arezoo8799@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of microneedling and phenytoin cream 1% compared to microneedling in atrophic scars caused by facial acne: a double-blind randomized clinical trial

Public title

Evaluation of the effect of microneedling and phenytoin cream on atrophic scars compared to microneedling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with atrophic facial acne scars aged 18-45 years
Patients with skin type 1-4

Exclusion criteria:

Sensitivity to phenytoin. Patients who have received laser treatment in the last three months. Patients with active colloidal scar or active skin lesion at the injection site. History of malignancy or receiving chemotherapy.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **25**

More than 1 sample in each individual

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

Each patient is considered both control group and intervention group. One side of the face is the control group and the opposite side is the intervention group.

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is random among patients referred to Hazrat Rasool Akram Hospital. The randomization method is simple. Our tool is to randomize the table of random numbers and place them inside sealed bags. Each bag contains the letters A or B: A: for the group receiving microneedling and phenytoin cream on the right and only microneedling on the left side of the face. B: for the group receiving microneedling and phenytoin cream on the left and only microneedling on the right side of the face.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and 2 evaluating dermatologists will be blinded to which side of the face received microneedling and phenytoin. Also, they will not know which side of the face is the only microneedling done..

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hazrat Rasool Akram hospital, Mansoori avenue, sattarkhan street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2021-08-17, 1400/05/26

Ethics committee reference number

IR.IUMS.FMD.REC.1400.332

Health conditions studied

1

Description of health condition studied

Atrophic Scars

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

Qualitative intensity of atrophic scar

Timepoint

1-At the beginning of the study, 2- before the second turn 3- before the third turn. 4. Two months after the end of the treatment period

Method of measurement

Photography by visioface. Objective observation. Visioface a full face photographic method for facial skin analysis. It has an accurate software to take high resolution full face photos and allows faster image capture with automatic skin type classification. By processing these images, skin problems are identified.

Secondary outcomes

1

Description

Quantative intensity of atrophic scars

Timepoint

1) At the beginning of the study. 2) Before the second turn 3) Before the third turn. 4) Two months after the end of the treatment period.

Method of measurement

Determine the depth of the scar by shooting by visioface, Scoring with Baron and Goodman scale

2

Description

Adverse events

Timepoint

1) At the beginning of the study. 2) Before the second turn 3) Before the third turn. 4) Two months after the end of the treatment period.

Method of measurement

Patient report, physician diagnosis

3

Description

The rate of improvement of scar

Timepoint

1) At the beginning of the study. 2) Before the second turn 3) Before the third turn. 4) Two months after the end of the treatment period.

Method of measurement

Patient satisfaction, photography by visioface, physician diagnosis

Intervention groups

1

Description

Intervention group: The intervention group is patients suffering from Atrophic scar lesion. The intervention group will be treated with microneedling and 1% Phenytoin topical cream, made by Medifarm company, three times a day for a week. The number of microneedling sessions will be monthly for three months (with an interval of one month and three times). Nysoya machine and 36 needle cartridges will be used for microneedling. The speed of the microneedling device will be set at 100 Hz and the penetration depth of the needles will initially be half a millimeter. Then the depth of penetration of the needles will gradually increase until there is a bleeding pinpoint on the skin. The handpiece will be done perpendicular to the skin as well as horizontally and rotationally, and spot bleeding during microneedling will be cleared with normal sterile saline. Local anesthesia using Xylopi topical cream will be performed one hour before the intervention on patients. After the intervention, the face will be washed with normal saline.

Category

Treatment - Other

2

Description

Control group: All steps performed for the intervention group will be repeated for the control group, except that the control group will be treated with microneedling and Mupirocin cream only three times a day as a placebo for one week. It should be noted that each patient is

considered both control group and intervention group. One side of the patient's face will be the control group and the opposite side will be the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram hospital

Full name of responsible person

Dr.Afsaneh Sadeghzadeh Bazarghan

Street address

Hazrat Rasool Akram hospital, Niyayesh avenue, Sattarkhan street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Seyyed Abbas Motevallian

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Tehran

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Sadeghzadeh Bazarghan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

Iran University of Medical Sciences

Full name of responsible person

Arezoo Pashaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Afsaneh Sadeghzadeh Bazarghan

Position

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Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street addressHazrat Rasool Akram, Niyayesh Ave, Sattarkhan
street, Tehran, Iran**City**

Tehran

Province**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**Undecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be 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**

Not applicable