Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effectiveness of needling technique with topical Latanoprost in treatment of hypopigmented burn scars in burn patients

Protocol summary

Study aim

The effectiveness of needling technique with topical Latanoprost in treatment of hypopigmic burn scars.

Design

Clinical trial, control group, microneedling with Latanoprost drops, Parallel groups, double blind, simple randomization, sample size of 30

Settings and conduct

The study is conducted in Motahari Burn Hosppital. The placebo is sent to the therapist in similar containers of Latanoprost drops labeled patient names with similar dose. Patient, dermatologist, plastic surgeon assessing the outcome (scar) and data analyst, are blind to study groups. Before treatment, 3 and 6 months later, scars are photographed and scored.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 15-50 years, having hypopigmented scars, willing to cooperate and follow-up on treatment and complete the informed consent form and exclusion criteria: pregnancy, planning to become pregnant, or breastfeeding, having severe systemic diseases in the past 6 months, concomitant diseases (diabetes, connective tissue disease, chronic kidney disease, cardiovascular disease) and any type of disease causing immune system dysfunction and delay wound healing, immunosuppressant drugs and corticosteroids, using depigmented or pigmented products on scars during the past 3 months, history of allergy or high sensitivity to the compounds used in the study, smoking and alcohol consumption and since the onset of a lesion leading to hypopigmented or depigmented scars, only 6 months have passed.

Intervention groups

Intervention group 1: needling + Latanoprost ointment in one limb; Intervention group 2: needling + placebo in one limb; Control group: symmetrical limb in both intervention groups without treatment

Main outcome variables

Scarring is compared in all patients using the 0-4 scale (resizing and colorimetric), Vancouver Scar Scale, patient satisfaction by visual analog scale and treatment cost.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111123008177N18**
Registration date: **2018-09-18, 1397/06/27**
Registration timing: **prospective**

Last update: **2018-09-18, 1397/06/27**
Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Mohammad Javad Fatemi

Name of organization / entity

Burn Research Center of Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of needling technique with topical Latanoprost in treatment of hypopigmented burn scars in burn patients

Public title
Needling technique with topical Latanoprost in treatment of hypopigmented burn scars
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 15-50 years. In two symmetrical regions of the body (focusing on the organs) having hypopigmented scars. Willing to cooperate and follow-up on treatment and complete the informed consent form.
Exclusion criteria:
Patients who are pregnant, are planning to become pregnant, or are breastfeeding. Those who have had severe systemic diseases in the past 6 months. Concomitant diseases (diabetes, connective tissue disease, chronic kidney disease, cardiovascular disease) and any type of disease that can cause immune system dysfunction and delay wound healing. Immunosuppressant drugs and corticosteroids. History of the use of depigmented or pigmented products on scars during the past 3 months. Have a history of allergy or high sensitivity to the compounds used in the study. Smoking and alcohol consumption. Since the onset of a lesion leading to hypopigmented or depigmented scars, only 6 months have passed.
Age
From **15 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients in group (A) in one limb will be treated with needling + latanoprost ointment and in symmetrical limb without treatment and in group (B) in one limb needling + placebo treatment and in symmetrical limb without treatment.
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who have the inclusion criteria are enrolled in the study. Assigning the treatment type to either of the two same areas is done by simple randomization by software.
Blinding (investigator's opinion)
Double blinded
Blinding description
To do blinding process, the placebo drops similar to those of Latanoprost are prepared and used simultaneously with the same dose. Patients who participate, main researchers of the study, dermatologist who perform the microneedling technique, the plastic surgeon examining the outcome of patient's scar before and after the intervention, and ultimately the person who is analyzing the data are blind to the study.
Placebo
Used
Assignment
Parallel
Other design features
Patients in both groups (A) and (B) are treated in one limb and untreated in the other limb. Therefore, each intervention group will have a control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Central building of Iran University of Medical Sciences, next to Milad Towe, Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-06-26, 1397/04/05
Ethics committee reference number
IR.IUMS.REC.1397.029

Health conditions studied

1

Description of health condition studied
Hypopigmented scar
ICD-10 code
L81.6
ICD-10 code description
Other disorders of diminished melanin formation

Primary outcomes

1

Description
Scar
Timepoint
Before intervention, 3 and 6 months after using the last dose of drops
Method of measurement
0-4 scale (including resizing and colorimetric staining) and Vancouver Scar scale

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
Before intervention, 3 and 6 months after using the last dose of drops
Method of measurement
Visual Analog Scale

2

Description
Cost
Timepoint
The end of the study
Method of measurement
Estimated cost of microneedling process and latanoprost drops

Intervention groups

1

Description
Intervention group 1: Needling procedure is performed under local anesthesia on the hypopigmented or depigmated organs of the patient, measuring from 4 to 25 cm square. The German AMIEA MED microneedling is a DA-3.0-EN-MP type approved by CE Europe, ISO 13485, and the Ministry of Health. Then, a drop of latanoprost (0.005%, 50 µg / ml, Iran, Sina drug) is applied to the patient. The dose is one drop per 2 × 2 cm area twice daily for 24 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: Needling procedure is performed under local anesthesia on the hypopigmented or depigmated organs of the patient, measuring from 4 to 25 cm square. Then placebo drops containing distilled water are used. The dose is one drop per 2 × 2 cm area twice daily for 24 weeks.
Category
Placebo

3

Description
Control group: Symmetrical limb will be left untreated in each patient.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Burn Hospital
Full name of responsible person
Mahnoush Momeni
Street address
Motahari Burn hospital, Yasemi St., Vali-e-asr Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Central building of Iran university of Medical sciences, next to Milad Tower, Hemmat highway
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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

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mahnoush Momeni

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Burn

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study protocol, informed consent form, and clinical study report will be shared

When the data will become available and for how long
Access period 1 month after printing the article

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Documentation will be possible by mentioning the main source

From where data/document is obtainable
Scientific respondents of study: - Dr. Saeed Shafieyan Burn Research Center, Motahari Burn Hospital, Rashid Yasemi St., Vali-e-Asr Ave. 00982188884275

sshafiiyan@yahoo.com

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

The request is sent by e-mail or by telefax. After the approval of scientific respondents, the study will be available to the applicant

Comments