Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 2026

Evaluation of Efficacy of BBSB type C in comparison with needle subcision on atrophic acne scar

Protocol summary

Study aim
Determine the efficacy and safety of subcision with barikbins-blunt-subcision-blade type C in comparison with Needle No. 22 in the treatment of atrophic acne scars

Design
In this study, 32 patients with atrophic acne scars in both sides of their face referred to Shahdai Hospital during the period of 1395 to 1396 were evaluated for inclusion criteria and exclusion criteria.The two sides of the face are randomly divided into two groups A and B, and analysts and patients are not aware of the type of group and only the surgeon is aware of the study group.

Settings and conduct
This randomized clinical trial was conducted in patients with atrophic acne scars in two parts of their face who referred to laser clinic of Shohadaye Tajrish Hospital. The two sides of the patients were randomly divided into two groups, and analysts and patients are unaware of the type of group and only the surgeon is aware of the study group.

Participants/Inclusion and exclusion criteria
Inclusion criteria : age 18 to 50 years; complete patient satisfaction; participation in atrophic acne scars on both sides of the species with relatively similar severity on both sides; Exclusion criteria: active nodulosistic acne (more than 6 papules or nodule on each side of the face); active skin infection (for example, herpes simplex or jaundice infection); hematological disorders or coagulopathy; Immunosuppression; dermatological diseases interact with the procedure; previous history of colloid; use of medications that prolong the bleeding time (especially aspirin, warfarin or vitamin E); isotretinoin in the last 12 months; resurfacing in 6 Last month included dermabrasion, laser therapy, chemical peeling; pregnancy or breastfeeding;

Intervention groups
Face A side: Under subcision with BBSB type C. Face B side: Perform subcision with the needle number 22.

Main outcome variables
Severity of atrophic scars

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111121008146N29**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date
2018-01-21, 1396/11/01

Registrant information

Name
Mohammadreza Razaghi

Name of organization / entity
Laser application in medical sciences research center

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-19, 1395/12/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2015-03-21, 1394/01/01

Actual recruitment end date

2016-03-20, 1395/01/01

Trial completion date

empty

Scientific title

Evaluation of Efficacy of BBSB type C in comparison with needle subcision on atrophic acne scar

Public title

The effect of subcision on acne scar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 50 years old Patient's complete consent to participate in the study Acne atrophic scars on both sides of the species with a relatively uniform intensity on both sides

Exclusion criteria:

Active nodulosistic acne (more than 6 papules or nodules on each side of the face) Active skin infection (herpes simplex or jaundice infection) Hematological disorders or coagulopathy Immunosuppression Dermatological diseases interfere with the procedure Previous biography of colloids Taking medications that prolong the bleeding time (especially aspirin, warfarin or vitamin E) Isotretinoin intake over the past 12 months Performing resurfacing procedures over the past 6 months include dermabrasion, laser therapy, chemical peeling Pregnancy or breastfeeding

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **32**

More than 1 sample in each individual

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

One side of the face treated with subcision and the other side treated with needle.

Actual sample size reached: **32**

More than 1 sample in each individual

Actual sample size in each individual: **2**

One side of the face treated with subcision and the other side treated with needle.

Randomization (investigator's opinion)

Randomized

Randomization description

The patient's face are divided into two intervention groups 1 and 2 according to a simple randomized 1: 1 random number table. The analyst and the patient are not aware of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The group and side of the face are placed in pairs and in dark envelopes. It is available to the surgeon and only the surgeon is informed of the patient's healing side. Procedures in this project are done by a skilled dermatologist. The envelope will be opened by a physician only after initial evaluations in each person, and neither patients nor analysts will be aware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2017-02-05, 1395/11/17

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.927

Health conditions studied

1

Description of health condition studied

Atrophic acne scar

ICD-10 code

L99

ICD-10 code description

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

Primary outcomes

1

Description

Severity of atrophic scars

Timepoint

Before starting treatment, in the first week after treatment, the first month, the third month and the sixth month after treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:The A side is required to be subcision to BBSB type C. The site of the entry of the subcision blade is at a point in the 1 cm front and 2 cm ahead of the ear tragus. Iodine is used to sterilize the area. Tomsent solution is combined with 50 cc of lidocaine, 1% pure, 1 cc epinephrine, 0.1% and 10 cc of sodium bicarbonate solution, 4.2% in normal saline 1 liter for local anesthetic. 50 to 100 cc of this solution is injected in a sub-dermal plaque with gauge 23 needle at 4 to 7 dots. For subcision, BBSB type C is used. Through the inlet area that has already been identified and numb, the blade number C is entered on the parallel plan with the skin on the subdermal plate and the smooth surface of the blade is facing up (the index of the thumb is on the handle to indicate it) All fibrous bands are released by moving forward and backward, and by moving the pseudo-fan, the blade is moved to the adjacent portions. The blade is moved slowly to avoid excessive force and damage to the nerves and vessels and to the skin. Also, the lack of movement of the blade to the lateral will also help prevent this damage. About two-thirds of the length of the blade can be entered into the skin and used from an entrance area for the entire scar area of the face side. After the procedure, an antibiotic with an without pressure gas for simple dressing is used. Oral antibiotics or anti-viral antibiotics are prescribed according to individual needs. Patients are educated about the possibility of edema, bruising, mild thrombosis in the first few days. Patients are advised to sleep semi sitting for two nights to reduce swelling.

Category

Treatment - Devices

2

Description

Intervention group2: On the B side, perform the subcision with the needle number 22. After determining the range and location of atrophic scars with non-toxic surgical markers, the range is averaged by about 10 cc of lidocaine-2% pure without epinephrine. For subcision, 22-gauge needles are used for deep-scarves and 27-gauge scarves for surface scars attached to a 1-cc syringe. The skin of the patient is pinched or stretched by a non surreptitious surgeon to make the skin firm and non-moving. By inserting the needle from the proximal axial atrophic scar, the fibrous bands are released by forward movement and lateral movement in parallel planes of the skin and in the scars area and about 1 mm from the margin. For each atrophic scar, at least one entry point and sometimes a needle insertion area are required. The ultimate goal is to move the needle from the horizontal to the lateral, along with a mild hematoma in the atrophic scar region and a swelling in the surface of the scar. Hemostasis is done by placing a non-pressure gas in the area. The maximum number of atrophic scars in the patient's range will be treated on that side. After the procedure, an antibiotic with an without pressure gas for simple dressing is used. Oral antibiotics or anti-viral antibiotics are prescribed according to individual needs. Patients are educated about the possibility of edema, bruising, mild thrombosis in the first few days. Patients are advised to sleep semi sitting for two nights to reduce swelling.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohadaye Tajrish Hospital

Full name of responsible person
Dr Behrouz Barikbin

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Sponsors / Funding sources

1

Sponsor

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Email
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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
Shahid beheshti 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
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Position
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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
Undecided - It is not yet known if there will be a plan to make this available