Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the efficacy and safety of botulinum toxin type A injection with cross-linked hyaluronic acid in comparison with non cross-linked hyaluronic acid in the treatment of patients with icepick acne scar: A double blind controlled randomized clinical trial

Protocol summary

Study aim
Evaluation of the efficacy and side effects of botulinum toxin type A injection with cross linked hyaluronic acid in comparison with non cross linked hyaluronic acid in the treatment of icepick acne scar

Design
Clinical trial with two intervention groups, parallel, double-blind, randomized, phase 3 on 16 patients, randomized with sealed envelopes

Settings and conduct
For injection, botulinum toxin type A is diluted with normal saline and then, depending on the extent of the scar and the area being treated, each volume of Dysport is drawn into a 1 cc syringe, five times mixed and diluted with hyaluronic acid (cross linked or non cross linked). The patient does not know in which treatment group he is. The data are also evaluated by the patient himself and a blind dermatologist and finally the statistical specialist, who also does not know which drug combination was injected in each group, analyzes the results of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with icepick acne scars in the range of 18 to 40 years Exclusion criteria: active acne, inflammation or active infection of herpes at the procedure site, hemodynamic instability, taking anticoagulant or NSAID during the previous 48 hours and also patients with platelet dysfunction or thrombocytopenia, serious internal disease, comorbidity at the treatment site

Intervention groups
Group 1: Injection of botulinum toxin type A and cross linked hyaluronic acid, Group 2: Injection of botulinum toxin type A and non cross linked hyaluronic acid

Main outcome variables
Qualitative and quantitative severity of scar with Visioface, The rate of improvement with Global Aesthetic Improvement Scale (GAIS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210718051930N1**
Registration date: **2021-07-30, 1400/05/08**
Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**
Update count: **0**

Registration date
2021-07-30, 1400/05/08

Registrant information

Name
Abbas Dehghani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-06, 1400/06/15

Expected recruitment end date
2022-04-04, 1401/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of botulinum toxin type A injection with cross-linked hyaluronic acid in comparison with non cross-linked hyaluronic acid in the treatment of patients with icepick acne scar: A double blind controlled randomized clinical trial

Public title

Comparison of the effect of combining botulinum toxin and cross-linked hyaluronic acid with non cross-linked hyaluronic acid in the treatment of icepick acne scar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with icepick acne scar in the range of 18 to 40 years Having informed consent to participate in the study Possibility to attend visit and follow-up sections

Exclusion criteria:

Active acne Inflammation or herpes simplex virus infection at the site of the procedure Taking anticoagulants or NSAIDs within 48 hours before and in patients with platelet dysfunction or thrombocytopenia Serious internal disease Accompanying disease at the treatment site

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

After being selected by available method, patients are divided into two groups by simple randomization, so that among 16 sealed bags, one bag will be randomly selected for each patient. Each bag contains the letter a or b: a for the group receiving botulinum toxin type A and cross-linked hyaluronic acid and b for the group receiving botulinum toxin type A and non cross-linked hyaluronic acid.

Blinding (investigator's opinion)

Double blinded

Blinding description

For group a patients, a combination of botulinum toxin type A and cross-linked hyaluronic acid is injected once, and for group b patients, a combination of botulinum toxin type A and non cross-linked hyaluronic acid is injected twice with a month interval. The patient does not know in which treatment group he is. In order to evaluate, in two groups, before treatment, 1 month later and then 3 and 6 months after one month follow-up, the severity of icepick scars is measured qualitatively and quantitatively by Visioface and also the rate of improvement with Global Aesthetic Improvement Scale (GAIS) is determined by the patient and a blind dermatologist. Finally, the statistician, who also does not know which drug combination was injected in each group, analyzes the results of the study.

Placebo

Not 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 scinces

Street address

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

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2021-07-03, 1400/04/12

Ethics committee reference number

IR.IUMS.FMD.REC.1400.255

Health conditions studied

1

Description of health condition studied

icepick acne scar patients

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

Qualitative intensity of scar

Timepoint

At the beginning of the study, 1 month later and then 3 and 6 months later

Method of measurement
Photography with Visioface

2

Description
Quantitative intensity of scar
Timepoint
At the beginning of the study, 1 month later and then 3 and 6 months later
Method of measurement
Determine the depth of the scar by photography with Visioface

3

Description
The rate of improvement in scar
Timepoint
1 month after starting treatment and then 3 and 6 months later
Method of measurement
according to Global Aesthetic Improvement Scale (GAIS)

Secondary outcomes

1

Description
Side effects
Timepoint
1 month after starting treatment and then 3 and 6 months later
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention group 1: For patients in this group, a combination of botulinum toxin type A and cross-linked hyaluronic acid is injected once. For injection, botulinum toxin type A: Dysport® (abobotulinumtoxinA) with 300 units/vial is dissolved with 2 cc of normal saline and then, depending on the extent of the scar and the treated area, each volume of Dysport is drawn in the BD lower lock syringe, is mixed and diluted five times with cross-link hyaluronic acid through the interface 30 times. So that each small line of BD syringe contains 0.6 units of Dysport (microbotax). Cross-link hyaluronic acid used has low G prime of the NEAUVIA 22mg or INTENCE / REOLOGY brand. This injection is performed after local anesthesia with XylaP cream for 45 minutes and then wiping it with an alcohol swab, with Gauge 27 mesotherapy needle and under the scars intradermally.
Category
Treatment - Drugs

2

Description
Intervention group 2: For patients in this group, a combination of botulinum toxin type A and non cross-linked hyaluronic acid is injected twice with 1 month interval. For injection, botulinum toxin type A: Dysport® (abobotulinumtoxinA) with 300 units/vial is dissolved with 2 cc of normal saline and then, depending on the extent of the scar and the treated area, each volume of Dysport is drawn in the BD lower lock syringe, is mixed and diluted five times with non cross-link hyaluronic acid through the interface 30 times. So that each small line of BD syringe contains 0.6 units of Dysport (microbotax). Non cross-link hyaluronic acid used has REVITACARE 532 CYTOCARE brand. This injection is performed after local anesthesia with XylaP cream for 45 minutes and then wiping it with an alcohol swab, with Gauge 30 mesotherapy needle and under the scars intradermally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool Akram hospital
Full name of responsible person
Elham Behrangi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
35

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
Elham Behrangi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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

Not applicable