

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of botulinum toxin A injection by microneedling with intradermal injection by syringe in the treatment of patients with open pores

Protocol summary

Study aim

Comparison of the effect of botulinum toxin A injection by microneedling with intradermal injection by syringe in the treatment of patients with open pores

Design

A clinical trial parallel groups, single-blind, phase 3 on 35 patients. Non-random,

Settings and conduct

Samples will be selected from patients referred to Isfahan University of Medical Sciences. Before and one month after the intervention, photography and dermoscopy are performed on both sides of the face. Photography is evaluated by two non-performing dermatologists with the Quartile improvement scale and with the Likert satisfaction scale, patients express their satisfaction.

Participants/Inclusion and exclusion criteria

Patients of both sexes, from 25 years to 60 years and with different duration of infection are selected and open pores with different intensities Exclusion criteria: Retinoid use in the last three months, laser or peeling in the last 6 months, myasthenia gravis, pregnant and lactating women, history of allergic reaction to botulinum toxin

Intervention groups

After local anesthesia at the treatment site, botulinum toxin A is used for use at a concentration of 100 units in 2.5 ml with 9% normal saline, then in syringes of one cc with a gauge of 30, so that each syringe contains 20 units. We prepare it from botulinum. Then, on one side of the face, treated with 24-tooth microneedling to a depth of 3 to 3.5 mm, we then apply 50 units of botulinum on the site, and on the other side of the face, we inject 50 units of the solution into the dermis with a syringe.

Main outcome variables

the Quartile improvement scale. Likert satisfaction scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052723N2**

Registration date: **2022-07-01, 1401/04/10**

Registration timing: **prospective**

Last update: **2022-07-01, 1401/04/10**

Update count: **0**

Registration date

2022-07-01, 1401/04/10

Registrant information

Name

Mahya Abedini

Name of organization / entity

Country

Iran (Islamic Republic of)

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aabedini.ma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-22, 1401/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of botulinum toxin A injection by microneedling with intradermal injection by syringe in the treatment of patients with open pores

Public title

Evaluation of the effect of different microbotox methods in the treatment of open pores

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent to participate in the study Age over 25 years No history of allergic reaction to botulinum toxin

Exclusion criteria:

Taking topical retinoids or oral isotretinoin in the last three months Laser or chemical peels during the last 6 months Myasthenia Gravis Pregnant and lactating women

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Dermoscopy and photography will be evaluated by two Non-performing dermatologists will be evaluated.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

No. 58, Shania Madanian Ave, Behdari Lashgar Street, A rtesh Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174755636

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.ARI.MUI.REC.1401.069

Health conditions studied

1

Description of health condition studied

Dilated pores

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dermoscopic changes

Timepoint

Before and one month after

Method of measurement

Dermoscopy (number of pores and their size in a specific area) by examining shallow holes, holes filled with keratotic plugs and yellow spots

2

Description

the Quartile improvement scale

Timepoint

One month after doing

Method of measurement

Photographs will be taken before and one month after treatment and the pore size improvement will be evaluated by two dermatologists who are blind to the study with the Quartile improvement scale (0-4 scale) as follows (11).) 0 = No improvement 1 = Minor / mild improvement (1% -25%) 2 = Moderate improvement (26% -50%) 3 = Marked improvement (51% -75%) 4 = Very significant improvement (76% -100%)

3

Description

Likert satisfaction

Timepoint

One month after work

Method of measurement

Also, one month after treatment, the Likert satisfaction criterion (1-5 scale) will be used to assess patient satisfaction. (11) 1 = Very dissatisfied 2 = Dissatisfied 3 = Neither satisfied nor dissatisfied 4 = Satisfied 5 = Very satisfied

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Using local anesthesia at the treatment site, which remains on the site for half an hour, then the site is washed with normal saline and sterilized using aseptic solution. Then botulinum toxin A (dyston)for use in patients is concentrated to 100 units in 2.5 ml with 9% normal saline, then in syringes of one cc with 30 gauge, so that each syringe contains 20 units of botulinum is prepared Then we treat one side of the face with 24-tooth microneedling to a depth of 3 to 3.5 mm until the pinpoint bleeding is continued.Then we use botulinum material on the spot so that 50 units of solution are used on one side of the face.

Category

Treatment - Devices

2

Description

The second intervention group: On the other side of the face, we make one cc with the pre-prepared syringes at a distance of one centimeter inside each dermis so that a delicate protrusion is created and 50 units of the solution are used.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mahya Abedini

Street address

Soffe st, Alzahra hospital

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2

Recruitment center

Name of recruitment center

SedigheTahere hospital

Full name of responsible person

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<http://www.paziresh24.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

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Vice President for Research and Technology, Building No. 4, University of Esfahan, Hezar jerib St

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research@mui.ac.ir

Web page address

<http://research.mui.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences
Full name of responsible person
Mahya Abedini
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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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

At the end of the study, study protocol, statistical analysis and clinical study report, the informed consent form, the codes used in the data analysis and the data dictionary can be shared with other researchers.

When the data will become available and for how long

Access period starts one month after the results are published

To whom data/document is available

Data will be available to researchers working in academic and scientific centers

Under which criteria data/document could be used

Researchers can use the findings and data of this study in their research by submitting a document that proves their employment in scientific and academic centers.

From where data/document is obtainable

Researchers can receive study data via sending an E-mail to researcher E-mail: Aabedini.ma@gmail.com phone number: 09128021807 Dr Mahya Abedini address: , Behdari lashgar Ave, Artesh Blv, Isfahan, Iran

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

Researchers can send an email to the address to indicate the type of data they need, and after reviewing their request, the information will be sent to them via email.

Comments