Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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

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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 improvement1 = 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 dissatisfied2 = Dissatisfied3 = Neither satisfied nor dissatisfied4 = Satisfied5 = 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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Street address
Vice President for Research and Technology, Building No. 4,University of Esfahan, Hezar jerib St
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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
Dermatology

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Person responsible for updating data

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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