

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Evaluation of the effect of botulinum toxin injection in comparison with botulinum toxin injection and PROFHILO hyaluronic acid in rejuvenation of the neck.

Protocol summary

Study aim

Comparative study of the effect of Botox injection with a combination of Botox injection and Profilo gel in reducing neck lines

Design

Randomized, parallel group trial with blinded outcome assessment on 20 patients using Block Randomization method and Random Allocation software for randomization.

Settings and conduct

20 patients with neck rejuvenation request in Razi Hospital, Tehran in the first visit receive toxin dysport injection for horizontal neck lines, 2 weeks later 10 patients will be visited again and the first injection of profhilo filler will be performed in horizontal neck lines which will be repeated 1 month later. Paraclinical evaluation will be performed for elasticity , hydration , rate of epidermal water loss and the thickness and density of the dermis and epidermis at the first visit and 6 months after the last injection. physicians evaluating the outcome are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults over 18 and under 70 with wrinkle severity rating scale between 2-4. Exclusion criteria: systemic uncontrolled disease, history of fillers or Botox injections in lower face and neck in the past 12 months.

Intervention groups

Control group:10 Participants will be injected with Dysport toxin (IPSEN company) with a total dose of 40 to 70 units in the initial visit. Intervention group :10 Participants will be injected with Dysport toxin with a total dose of 40 to 70 units at the initial visit. 2 weeks later, these patients will be injected with 2 cc of Profilo gel (IBSA Company), and one month after the first injection of Profilo filler, the second time will be injected with another 2 cc.

Main outcome variables

wrinke severity rating scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201204049589N1**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Asma Jabbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 0553

Email address

jabbari.asma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of botulinum toxin injection in comparison with botulinum toxin injection and PROFHILO hyaluronic acid in rejuvenation of the neck.

Public title
Evaluation of the effect of botulinum toxin and Profhilo hyaluronic acid injection in rejuvenation of the neck.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Adults over 18 years and under 70 years Signing a voluntary agreement WSRS (Wrinkle Severity Rating Scale) between 4 - 2 They do not want to have a surgical procedure Patients who are not candidates for surgery
Exclusion criteria:
 Pregnancy and breastfeeding Neuromuscular diseases such as myasthenia gravis• Hypersensitivity to Botox or human albumin• Uncontrolled systemic disease Infection, scarring, abnormality at the injection site History of Botox injection or lower face filler in the last 12 months Patients treated with aspirin, immunosuppressants, narcotics, antiDepressants and corticosteroids in the last 3 months

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method Using Random Allocation software, 20 patients are assigned to two groups of 10.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, physicians evaluating the outcome without knowing the patient's treatment group, based on a review of pre- and post-treatment photographs compared to the Wrinkle Assessment Scale, record their observational information.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Floor 5, Central Building of Tehran University of Medical Science, Qods St, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.064

Health conditions studied

1

Description of health condition studied

Horizontal neck lines

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

wrinkle severity rating scale (WSRS)

Timepoint

The first visit and 6 months after Dysport injection and the second time filler

Method of measurement

Score based on the severity of wrinkles by comparing photography and dermoscopy before and after treatment.

Secondary outcomes

1

Description

skin hydration

Timepoint

Baseline visit and 6 months after the second filler injection in one group and one time of receiving dysport in the second group.

Method of measurement

probe of the MP bolagen multi-adapter device(corporatereg number 5562201656) to measure hydration of the skin

2

Description

skin elasticity

Timepoint

Baseline visit and 6 months after the second filler injection in one group and one time of receiving dysport in the second group.

Method of measurement

probe of the MP bolagen multi-adapter
device(corporatereg number 5562201656)

3

Description

Water loss from the surface of the epidermis

Timepoint

Baseline visit and 6 months after the second filler injection in one group and one time of receiving dysport in the second group.

Method of measurement

probe of the MP bolagen multi-adapter
device(corporatereg number 5562201656)

4

Description

pain during filler injection

Timepoint

During filler injection (two weeks after the first visit and one month after the second visit)

Method of measurement

Patient self-expression form

5

Description

dermis and epidermis density

Timepoint

Baseline visit and 6 months after the second filler injection in one group and one time of receiving dysport in the second group.

Method of measurement

Neck sonography

6

Description

dermis and epidermis thickness

Timepoint

Baseline visit and 6 months after the second filler injection in one group and one time of receiving dysport in the second group.

Method of measurement

Neck sonography

Intervention groups

1

Description

Control group: In 10 patients, Botulinum toxin (Dysport, IPSEN Company) injection will be performed in the

baseline visit according to the following protocol: 1 vial of Botox Dysport 500 units will be diluted with the addition of 2 and a half cc of normal saline. A 1 ml syringe with a 30 G needle will be used. In horizontal wrinkles, 1 to 2 intradermal injection units are performed at intervals of 1 to 2 cm. The maximum therapeutic dose is 70 units for the whole neck.

Category

Treatment - Drugs

2

Description

Intervention group: In 10 patients, Botulinum toxin (Dysport, IPSEN Company) injection will be performed in the baseline visit according to the following protocol: 1 vial of Botox Dysport 500 units will be diluted with the addition of 2 and a half cc of normal saline. A 1 ml syringe with a 30 G needle will be used. In horizontal wrinkles, 1 to 2 intradermal injection units are performed at intervals of 1 to 2 cm. The maximum therapeutic dose is 70 units for the whole neck. 2 weeks later, Profilla gel (IBSA Company) will be injected in these patients. The product is in the form of 2 ml syringes with 29G needle. The injection will be done transversely. 90 degree angle injection or deep platysmal injection should be avoided. The depth of the dermal injection will be deep dermis. The injection will be done at ten points and at each point 2 tenths of a cc. 1 month later, the 10 mentioned patients will receive the second time of Profilla gel with the same technique.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Asma Jabbari

Street address

Razi Hospital, Vahdat E Eslami Ave, Hafez Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Web page address
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 No
Title of funding source
 Tehran University of Medical Sciences
Proportion provided by this source
 40
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

2

Sponsor
Name of organization / entity
 IBSA Institute Biochemique SA
Full name of responsible person
 Armin Ghaedi
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 No. 60, unit1, 2nd floor, Maryam Sharghi Ave, Elahieh Ave
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 No
Title of funding source

Paezan Tejarat E Mehr company
Proportion provided by this source
 60
Public or private sector
 Private
Domestic or foreign origin
 Domestic
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 Industry

Person responsible for general inquiries

Contact
Name of organization / entity
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 Asma Jabbari
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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Full name of responsible person

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Position

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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

All data can be shared after people have been unidentifiable.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no other restrictions.

From where data/document is obtainable

Dr Asma Jabbari jabbari.asma@gmail.com

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

The data will be available via Email from the beginning of the publication of the results.

Comments