Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparative evaluation of the safety and efficacy of botulinum toxin type A (product of Imen Vaccine Alborz CO) in comparison with Dysport (standard treatment) for treating glabellar rhytids in people with moderate to severe glabellar rhytids.

Protocol summary

Study aim
Comparative evaluation of the safety and efficacy of botulinum toxin type A (product of Imen Vaccine Alborz CO) in comparison with Dysport (standard treatment) for treating moderate-to-severe glabellar rhytids

Design
Two arm parallel group randomized double blind active controlled trial with 140 participants

Settings and conduct
This clinical study is conducted on volunteers at the Center for research and training in skin diseases and leprosy. Before the intervention skin photograph will be taken for full face and frown lines, as well as blood and urine lab tests for the participants, then according to randomization code, the subjects will be treated with the relative drug (test or control). 14, 30, 60, 90 and 120 days later the skin photography will be repeated.

Participants/Inclusion and exclusion criteria
Men and women 18 to 75 years with moderate-to-severe glabellar rhytids who have not history of treatment with botulinum toxin in face area within the past 6 months and history of injectable filler, chemical peels and laser treatment within the past year and they have not also sensitivity to botulinum toxin

Intervention groups
Group 1: botulinum toxin type A (product of Imen Vaccine Alborz CO) 500iu vial, intra muscular injection, 40-60iu in 2.5 cc normal saline in 3 to 5 point in frontal area in one visit Group 2: Dysport (product of IPSEN) 500iu vial, intra muscular injection, 40-60iu in 2.5 cc normal saline in 3 to 5 point in frontal area in one visit

Main outcome variables
Subjects with improvement in GLSS one month (30 days) after treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150101020514N8**
Registration date: **2019-01-30, 1397/11/10**
Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **1**

Registration date
2019-01-30, 1397/11/10

Registrant information

Name
Alireza Firooz

Name of organization / entity
Tehran University of Medical Science

Country
Iran (Islamic Republic of)

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+98 21 8897 8190

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of the safety and efficacy of botulinum toxin type A (product of Imen Vaccine Alborz CO) in comparison with Dysport (standard treatment) for treating glabellar rhytids in people with moderate to severe glabellar rhytids.

Public title
evaluation the effect of botulinum toxin type A for treating frown lines

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women with 18 to 75 years old mild to moderate Glabellar Lines signing informed consent form

Exclusion criteria:
Hypersensitivity to botulinum toxin or other components of formulation History of treatment with botulinum toxin in face area within the past 6 months History of using aminoglycosides, penicillin, kinin, chloroquine,Calcium Channel Blockers, warfarin and aspirin History of injectable filler, chemical peels and laser treatment of any type within the past year Significant scarring ,skin disorder or wound infection in the facial area Neuro-muscular disorders like miastenia gravis, iron lambert , ALS Significant face asymmetry Any active, chronic and recurrent infection Pregnancy/ breast feeding

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Chain Generation performed using by R-CRAN version 3.2.3. We used randomized permutations, blocks (the size of each block is 4) for a total of 140 volunteers (1: 1 ratio). The codes will be labeled on the drugs. After ensuring the volunteer's eligibility and signing the informed consent form, a nurse will receive a code from the study site which will be used for random allocation of the drug to the candidate. The related drug will be injected for the volunteer. In this way, the volunteers fall into one of the two intervention groups and the volunteers' group and the type of drug they receive will not be disclosed to researchers or the study team.

Blinding (investigator's opinion)
Triple blinded

Blinding description
All volunteers will be examined by a specialist physician at the site of the study and the injection will be done at five points of the face muscles after examining eligibility for entry. Due to availability of the drug in the study site and sticking the research label on the medications and injections by the doctor, volunteer and the doctor will not be aware of the type of drug. The ICF has also met the purpose of the study and the volunteer knows that it will be randomly assigned to one of the two treatment groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Room 105 , 5th floor, Central construction of Tehran University of Medical Sciences, Ghods intersection, Keshavarz blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-12-27, 1397/10/06

Ethics committee reference number
IR.TUMS.VCR.REC.1397.708

Health conditions studied

1

Description of health condition studied
skin rejuvenation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
glabellar line severity scale

Timepoint
before intervention and 3, 7, 14, 30, 60, 90 and 120 days later

Method of measurement
physical examination

Secondary outcomes

1

Description
Percentage of subjects with improvement in Glabellar Lines at maximum frown
Timepoint
before intervention and 60, 90 and 120 days later
Method of measurement
GLSS

2

Description
Percentage of subjects with improvement in Glabellar Lines at resting
Timepoint
before intervention and 60, 90 and 120 days later
Method of measurement
GLSS

3

Description
Percentage of subjects with improvement in Glabellar Lines at maximum frown using SSA scoring
Timepoint
before intervention and 30 and 120 days later
Method of measurement
Subject Self Assessment (SSA)

4

Description
Percentage of subjects with improvement in Glabellar Lines at rest using SSA scoring
Timepoint
before intervention and 30 and 120 days later
Method of measurement
Subject Self Assessment (SSA)

5

Description
The onset and duration of the effect of two groups
Timepoint
Days 3, 7, 14, 30, 60, 90, 120 after treatment
Method of measurement
Clinical assessment

6

Description
Adverse effects
Timepoint
Days 3, 7, 14, 30, 60, 90, 120 after treatment
Method of measurement
Clinical assessment

Intervention groups

1

Description
Intervention group: botulinum toxin type A (product of Imen Vaccine Alborz CO) 500iu vial, intra muscular injection, 40-60iu in 2.5 cc normal saline in 3 to 5 point in frontal area in one visit
Category
Treatment - Drugs

2

Description
Control group: Dysport (product of IPSEN) 500iu vial, intra muscular injection, 40-60iu in 2.5 cc normal saline in 3 to 5 point in frontal area in one visit
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for Research and Training in Skin Diseases & Leprosy Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz
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No 415- Taleghani Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Imen vaccine alborz Company
Full name of responsible person
Maryam Amini Pouya
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Khaje Nasir Toosi Avenue
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Province
Alborz
Postal code
3331495894
Phone
+98 26 4533 4189
Email

info@imenvaccine.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Imen vaccine alborz Company

Proportion provided by this source

100

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

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

researcher

Latest degree

Medical doctor

Other areas of specialty/work

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Position

Professor of Dermatology

Latest degree

Specialist

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Medical doctor

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available