

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Phase IV study for assessment of the onset of action and Treatment Emergent Adverse Events of Dyston (Botulinum Toxin Type A- ImenVaccine Co.) in Glabellar Lines Improvement

Protocol summary

Registration timing: **prospective**

Study aim

The onset of action and safety Dyston during 14 days after injection will be evaluated in this study.

Last update: **2020-09-01, 1399/06/11**

Update count: **1**

Design

The single-arm, open-label phase IV clinical trial on 184 volunteers

Registration date

2020-05-21, 1399/03/01

Settings and conduct

The study site is in the skin operation room of Razi hospital in Tehran. After taking the informed consent and evaluating the eligibility criteria and the injection, the physician records the volunteer's information in the "Case Report Form". Also, a diary card for a 14-day following up will be given to them.

Registrant information

Name

Maryam Amini Pouya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

maryam.aminipouya@gmail.com

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male/female age of 18-75 years with moderate to severe glabellar lines at maximum frown. Exclusion criteria: History of aesthetic procedures on the glabellar area within the last 12 months, the medical condition that may affect neuromuscular function, history of facial nerve palsy, history of the eyelid or eyebrow ptosis, pregnant or lactating females

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intramuscular injection of Dyston (botulinum toxin type A- Imen vaccine Co.) into 3 to 5 injection sites of the glabellar area at the first visit.

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

2020-05-31, 1399/03/11

Actual recruitment end date

2020-06-15, 1399/03/26

Trial completion date

2020-06-29, 1399/04/09

Main outcome variables

Onset of action; treatment-emergent adverse events of Dyston within 14 days

General information

Reason for update

Study completion

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039672N3**

Registration date: **2020-05-21, 1399/03/01**

Scientific title

The Phase IV study for assessment of the onset of action and Treatment Emergent Adverse Events of Dyston (Botulinum Toxin Type A- ImenVaccine Co.) in Glabellar Lines Improvement

Public title

The onset of action and safety of Dyston in glabellar lines improvement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 75 year old volunteer Moderate to severe glabellar lines at maximum frown Signed an informed consent form Being agree with 14-day follow up

Exclusion criteria:

Hypersensitivity to botulinum toxin or any other ingredients in the formulation Taking the following medicines: aminoglycosides, penicillamine, quinine, chloroquine, hydroxychloroquine, calcium channel blockers, Anticoagulants (warfarin and aspirin) Any aesthetic surgery (e.g. fillers injection, chemical peeling, laser) or any other materials causing remodeling of the skin or active changes in the glabellar area within the last 12 months Previous history of any surgery in the facial muscles or scars in the glabellar area and the surrounding areas (including eyebrows) The medical condition that may affect neuromuscular function (e.g., myasthenia gravis, Eaton-Lambert syndrome, amyotrophic lateral sclerosis) History of facial nerve palsy Marked facial asymmetry History of the eyelid or eyebrow ptosis due to the facial muscle palsy Any active infection or acute skin disease in the injection sites Pregnant or lactating females

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **184**

Actual sample size reached: **184**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Vice-Chancellor in Research Affairs-Tehran University of Medical Science, 6th floor, at the corner of Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417614418

Approval date

2020-05-07, 1399/02/18

Ethics committee reference number

IR.TUMS.VCR.REC.1399.345

Health conditions studied

1

Description of health condition studied

Glabellar frown lines

ICD-10 code

R23.4

ICD-10 code description

Changes in skin texture

Primary outcomes

1

Description

The onset of action

Timepoint

Daily (immediately after injection till 14 days)

Method of measurement

Average (day)

2

Description

Adverse events

Timepoint

Daily (immediately after injection till 14 days)

Method of measurement

Percentage

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intramuscular injection of 0.2 to 0.3 milliliter from 500 unit vial of Dyston (botulinum toxin type A-Imen Vaccine Alborz) which is reconstituted in 2.5 milliliters of normal saline, into 3 to 5 injection sites in glabellar muscles at the first visit.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Amir Hooshang Ehsani

Street address

Vahdat Eslami St., Vahdat Eslami Sq.

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0553

Email

ehsanih@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Imen Vaccine Alborz

Full name of responsible person

Sajad Saeedifar

Street address

No. 110, Khajenasireddin Tousi street

City

Nazar Abad

Province

Alborz

Postal code

3331495900

Phone

+98 942 600 1123

Email

s.saeedifar@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

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

Person responsible for general inquiries

Contact

Name of organization / entity

Arta Zist Pharmed

Full name of responsible person

Maryam Amini Pouya

Position

Medical supervisor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Atam building, Niro street, South Jannat Abad

City

Tehran

Province

Tehran

Postal code

1473913108

Phone

0098219426001123

Email

m.amini@artapharmed.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi hospital

Full name of responsible person

Amir Hooshang Ehsani

Position

Specialist dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Vahdat Eslami street., Vahdat Eslami square

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0223

Email

ehsanih@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arta Zist Pharmed

Full name of responsible person

Elnaz Zabihi Eidgahi

Position

Medical Expert

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Atam building, Niro street, South Jannat Abad

City

Tehran

Province

Tehran

Postal code

1473913108

Phone

0098219426001123

Email

e.zabihi@artapharmed.com

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

Undecided - It is not yet known if there will be a plan to make this available