

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Study aim

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

Design

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

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.

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

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.

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**

Registration timing: **prospective**

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

Update count: **1**

Registration date

2020-05-21, 1399/03/01

Registrant information

Name

Maryam Amini Pouya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

maryam.aminipooya@gmail.com

Recruitment status

Recruitment complete

Funding source

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

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		sciences
Purpose	Treatment	Street address
Inclusion/Exclusion criteria		Vice-Chancellor in Research Affairs-Tehran University of Medical Science, 6th floor, at the corner of Qods street, Keshavarz boulevard
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	City
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	Tehran
Age	From 18 years old to 75 years old	Province
Gender	Both	Tehran
Phase	4	Postal code
Groups that have been masked	No information	1417614418
Sample size	Target sample size: 184 Actual sample size reached: 184	Approval date
Randomization (investigator's opinion)	N/A	2020-05-07, 1399/02/18
Randomization description		Ethics committee reference number
Blinding (investigator's opinion)	Not blinded	IR.TUMS.VCR.REC.1399.345
Blinding description		
Placebo	Not used	Health conditions studied
Assignment	Single	1
Other design features		Description of health condition studied
Secondary Ids	empty	Glabellar frown lines
Ethics committees		ICD-10 code
1		R23.4
Ethics committee		ICD-10 code description
Name of ethics committee	Ethics committee of Tehran University of Medical	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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elnaz Zabihi Eidgahi

Position

Medical Expert

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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

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