

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A Randomized, Double-blind, Phase III, Parallel, Active-controlled Clinical Trial to Evaluate the Non-inferiority of the Efficacy and Safety of Dyston in Comparison with Dysport for the Treatment of Chronic Migraine in Adults

Protocol summary

Study aim

Comparison of the Safety and Efficacy of Dyston with Dysport in the treatment of adult patients with chronic migraine; A Phase III, Randomized, Double-blind, Non-Inferiority Clinical Trial

Design

Controlled, double-blind, randomized, phase 3, sample size of 92

Settings and conduct

After assessing the eligibility criteria, CM patients will be enrolled to the study at Sina hospital, and randomized in a 1:1 ratio to receive either dyston or dysport after completing the 4 weeks baseline period. This study is double-blind (patient and physician), and consists of 4 visits (1 month interval) and the headache diaries will be assessed, after proper instruction on how they should be completed

Participants/Inclusion and exclusion criteria

Inclusion Criteria Men and women of 18 to 65 years
Diagnosis of CM according to ICHD-3 Informed and written consent. Exclusion Criteria Previous treatment with BonTA for CM and/ or cosmetic purposes with an interval of less than 3 months
Diagnosis of myasthenia gravis, Eaton-Lambert syndrome, ALS or any other significant disease that might interfere with neuromuscular function
Subject is currently participating or has participated in the last 3 months in another clinical study in which the subject has, is, or will be exposed to an investigational or non-investigational drug or device
Confirmed allergy to botulinum toxinA or any of the product components
Patients diagnosed with major depression
Patients diagnosed with any serious systemic diseases such as renal or hepatic failure, any other neurologic diseases like MS, epilepsy, and any other diseases that in the opinion of the investigator would put the patient at risk
Females of childbearing age with

confirmed or suspected pregnancy, those planning on conceiving during the trial duration and women who are breastfeeding

Intervention groups

Dyston or Dysport, up to 500 IU

Main outcome variables

50% responder rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049265N3**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

Registration date

2022-01-30, 1400/11/10

Registrant information

Name

Seyyedeh Maryam Afshani

Name of organization / entity

Arta Zist Pharmed

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-11-16, 1401/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized, Double-blind, Phase III, Parallel, Active-controlled Clinical Trial to Evaluate the Non-inferiority of the Efficacy and Safety of Dysport in Comparison with Dysport for the Treatment of Chronic Migraine in Adults

Public title

A Prospective, Phase III Clinical Trial to Evaluate the Non-inferiority of Dysport® to Dysport® for Chronic Migraine Treatment in Adults

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women of 18 to 65 years Diagnosis of chronic migraine (≥ 15 headache days a month for > 6 months) Headaches must have at least two of the following characteristics: unilateral location, pulsating quality, moderate-severe pain intensity and/or aggravation by or causing avoidance of routine physical activity (e.g. Walking or climbing stairs), nausea and/or vomiting, photophobia and phonophobia Informed and written consent

Exclusion criteria:

Previous treatment with botulinum toxin for chronic migraine Previous treatment with botulinum toxin for cosmetic purposes with an interval of less than three months Diagnosis of myasthenia gravis, Eaton-Lambert syndrome, amyotrophic lateral sclerosis or any other significant disease that might interfere with neuromuscular function Subjects not willing to comply with the study visits Subject is currently participating or has participated in the last 3 months in another clinical study in which the subject has, is, or will be exposed to an investigational or non-investigational drug or device Confirmed allergy to botulinum toxin-A or any of the product components Patients diagnosed with major depression Patients diagnosed with any serious systemic diseases such as renal or hepatic failure, any other neurologic diseases like multiple sclerosis, epilepsy, and any other diseases that in the opinion of the investigator would put the patient at risk Females of childbearing age with confirmed or suspected pregnancy, those planning on conceiving during the trial duration and women who are breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequencing of patients using random permutation blocks, blocks with the size of 4, for a total of 68 patients (1: 1 ratio) is generated online at sealedenvelope.com. The generated random sequence will be provided at the study site. According to each random code, anonymous codes are labeled on each vial (two intervention groups) and placed in the drug stock at the study site. After ensuring the patient's eligibility and obtaining informed consent, the assigned vial is injected for the patient according to the order specified in the randomization sheet.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be performed as a double-blind clinical trial. The appearance of both of the vials is made sure to be the same to maintain blinding of the physician. The patients will also be blinded to the assigned intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Central Headquarters of the Ministry of Health, Qods
Town, Tehran between South Flamek and Zarafshan
St., Treatment and Medical Education, Sima-ye-Iran
St.,

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۹۴۳۴۷۱

Approval date

2022-01-15, 1400/10/25

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1227

Health conditions studied

1

Description of health condition studied

Chronic migraine without aura

ICD-10 code

G43.7

ICD-10 code description

Chronic migraine without aura

2

Description of health condition studied

Chronic migraine with aura

ICD-10 code

G43.1

ICD-10 code description

Migraine with aura

Primary outcomes

1

Description

50% responder rate; meaning the proportion of patients with a $\geq 50\%$ decrease from baseline in the frequency of headache days.

Timepoint

baseline (week -4), week 0, week 4, 8, and 12

Method of measurement

Headache diary

Secondary outcomes

1

Description

30% responder rate; meaning the proportion of patients with a $\geq 30\%$ decrease from baseline in the frequency of headache days.

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

2

Description

Reduction of the duration of migraine attacks

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

3

Description

Reduction of the intensity of the migraine attacks

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

4

Description

Reduction of the patient's PHQ-9 depression score

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

5

Description

Improvement of the patient's quality of life according to HIT-6

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

6

Description

Reduction of the patient's disability scores according to MIDAS

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

7

Description

Incidence of any adverse events

Timepoint

Throughout the study period

Method of measurement

Headache diary

8

Description

Reduction of acute migraine medication consumption

Timepoint

Baseline (week -4), week 0, 4, 8, and 12

Method of measurement

Headache diary

Intervention groups

1

Description

1st Intervention group: Dyston®, 500 IU single-use, sterile vial for reconstitution, up to 500 units administered intramuscularly in the corrugator, procerus, superior frontalis, temporalis, splenius capitis, occipitalis, and the trapezius muscles

Category

Treatment - Drugs

2

Description

2nd Intervention group: Dysport®, 500 IU single-use, sterile vial for reconstitution, up to 500 units administered intramuscularly in the corrugator, procerus, superior frontalis, temporalis, splenius capitis, occipitalis, and the trapezius muscles

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Tehran, Iran

Full name of responsible person

Dr. Mansoureh Togha

Street address

Imam Khomeini St., Hassan Abad Square, Sina Hospital

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Imen Vaccine Alborz

Full name of responsible person

Setayesh Sadeghi

Street address

No. 110- Khajeh Nasir Tusi St.- Bahman St.- Sepehr Industrial Town- Nazarabad- Alborz- Iran

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Province

Alborz

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3331495900

Phone

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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

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

Arta zist pharmed

Full name of responsible person

Setayesh Sadeghi

Position

Medical department manager

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

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s.sadeghi@artapharmed.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arta zist pharmed

Full name of responsible person

Maryam Afshani

Position

Medical department supervisor

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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City

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Province

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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