Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Comparison of safety and efficacy of MASPORT® to commercial product in treatment of patients with glabellar lines

Protocol summary

Summary

The objective of this study is investigation of safety and efficacy of intramascular inection 50 U Botulinum toxin type A - MASPORT® - in compare to a commercial product- DYSPORT® - in adults with moderate to severe glabellar lines. Study design:This study is a double-blind, randomized ,parallel group, active-controlled, phase 3 clinical trial. Inclusion criteria: male or females; age 18 to 60 years with moderate to severe glabellar lines. Exclusion criteria: No sign of informed consent form; serious side effect; cardiovascular disorder; pulmonary infection/disorder; concomitant administration of neuromuscular drugs; face surgery or peeling. Population: 260 volunteers will be recruiting in this study. Intervention: Test group will receive 50 U of botulinum toxine type A -Masport intramascularly.The total dose will be injected in 5 different sites between glabellar lines.Active control group will receive 50 U of botulinum toxine type A -Dysport intramascularly.The total dose will be injected in 5 different sites between glabellar lines. All volunteers will subjected to follow-up visits 14,30,60,90 and 120 days after injection and all side effects and efficacy assessments will record in CFR forms. Primary outcome:Glabellar line improvement assessment by investigator on day 30 at maximum frown; Subject Global Assessment of Change (SGA) on day 30; Any side effects 0, 14 , 30,60,90 and 120 days after injection.secondary outcome: Glabellar line improvement assessment by investigator 60,90 and 120 days after injection at relax and maximum frown; Subject Global Assessment of Change (SGA) 60,90 and 120 days after injection. All data will analysis to confirm the non-inferiority of MASPORT® to DYSPORT® in glabellar line improvement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100214871N1**
Registration date: **2013-12-23, 1392/10/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-12-23, 1392/10/02

Registrant information

Name

Mohammad Taqavian

Name of organization / entity

Tehran Univercity of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Masoondarou Co./Avicena Scientific park of Tehran univercity of medical science.

Expected recruitment start date

2014-06-08, 1393/03/18

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of safety and efficacy of MASPORT® to commercial product in treatment of patients with

glabellar lines

Public title
Comparative study , safety and efficacy ,clinical trial phase III - of Masport in patients with glabellar lines, in compare to a commercial product
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: male or females; age 18 to 60 years old with moderate to severe glabellar lines. Exclusion criteria: No sign of informed consent form; serious side effect; cardiovascular disorder; pulmonary infection / disorder; concomitant administration of neuromuscular drugs; face surgery or peeling.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Study will be done as randomise and double blind (investigator and patient) for confirmation of non-inferiority of MASPORT® in compare to commercial product .

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee for Research Deputy of Tehran Univercity of Medical science
Street address
No 607,6'th Floor , Central Office of Tehran University of Medical science, Keshavarz Blv.
City
Tehran
Postal code
Approval date
2013-12-14, 1392/09/23
Ethics committee reference number
1896/130/92/ص

Health conditions studied

1

Description of health condition studied
Glabellar Line
ICD-10 code
L98.9
ICD-10 code description
Disorder of skin and subcutaneous tissue,unspecified

Primary outcomes

1

Description
Glabellar line improvement assessment by investigator.
Timepoint
Days 0 and 30 post-injection
Method of measurement
Investigator Rating of glabellar line severity at maximum frown and photography

2

Description
Subject Global Assessment of Change (SGA)
Timepoint
Days 0 and 30 post-injection
Method of measurement
Subject’s global assessment

3

Description
Any local and systemic side effects
Timepoint
At days 0, 14 , 30,60,90 and 120 post-injection
Method of measurement
Clinical evaluation

Secondary outcomes

1

Description
Glabellar line improvement assessment by investigator in maximum frown and at rest.
Timepoint
60, 90 and 120 days after injection .
Method of measurement
Investigator Rating of glabellar line severity at rest and maximum frown.

2

Description
Subject Global Assessment of Change (SGA)
Timepoint
Days 60;90 and 120 post-injection

Method of measurement
Subject's global assessment

Intervention groups

1

Description
Injection of 50 U botulinum toxin type A -MASPORT® in five injection site between glabellar lines in test group
Category
Treatment - Drugs

2

Description
Injection of 50 U botulinum toxin type A -DYSPORT® in five injection site between glabellar lines in control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Dermatology Hospital
Full name of responsible person
Dr Amir Hooshang Ehsani
Street address
Vahdat islami square, Vahdat islami Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Masoondarou Co.
Full name of responsible person
Dr Hossin Zolfagharian
Street address
No 98, 6th East st. Simindasht industrial City
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Masoondarou Co.
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Avicena Scientific park
Full name of responsible person
Dr. Mohammad reza Fazeli
Street address
North Kargar Avenue, PO Box: 14395-477
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Avicena Scientific park
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
School of Medicine, Tehran University of Medical Sciences
Full name of responsible person
Dr Amir Hooshang Ehsani
Position
Dermatologist, Associate Professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty