

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

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 intramuscular injection 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 toxin type A -Masport intramuscularly. The total dose will be injected in 5 different sites between glabellar lines. Active control group will receive 50 U of botulinum toxin type A -Dysport intramuscularly. The total dose will be injected in 5 different sites between glabellar lines. All volunteers will be subjected to follow-up visits 14, 30, 60, 90 and 120 days after injection and all side effects and efficacy assessments will be recorded 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 be analyzed 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 University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Masoondarou Co./Avicenna Scientific park of Tehran university 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

1896/130/92/ص

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 University 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

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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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