

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Study for safety and efficacy of intramuscular Administration of MASPORT® manufactured by Masoondarou Co. (phase 1 and 2)

Protocol summary

Summary

The objective of this study is to evaluate the safety , efficacy and dose finding of Masport® manufactured by Masoondarou Co. to treatment of glabellar facial lines. The trial is a monocentric study . Inclusion criteria: Male or females age 18 - 60 years with moderate to severe glabellar lines; exclusion criteria: evidence of any unusual condition in volunteers, evidence of pregnancy before administration of product and abnormal results of paraclinical tests. 12 volunteers will be enrolled in the study and each of the volunteers monitored for a maximum 4 months. Intervention is Masport® 500 unit vial manufactured by Masoondarou Co.. Volunteers will be injected by 1 dose of product in 5 sites. Primary endpoints includes efficacy measurements are the investigator's rating of glabellar line severity at maximum frown at day 30 post-injection, Subject's global assessment of change in appearance of glabellar lines at day 30 post-injection and occurrence any local and systemic adverse effects. A secondary efficacy endpoint is the investigator's rating of glabellar line severity at rest at day 30 post-injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201154536N2**

Registration date: **2012-01-30, 1390/11/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-01-30, 1390/11/10

Registrant information

Name

Naser Mohammadpour

Name of organization / entity

Masoon Darou Biopharmaceutical Co.

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Masoondarou Biopharmaceutical Co. & Research Deputy of Ministry of Health, Islamic Republic of Iran

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-20, 1391/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study for safety and efficacy of intramuscular Administration of MASPORT® manufactured by Masoondarou Co. (phase 1 and 2)

Public title

Study for effects of Masport in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male or females age between 18 to 60 years old with moderate to severe glabellar facial lines
Exclusion criteria: evidence of any unusual condition in volunteer, i.e.: severe allergic reactions, need for use of corticosteroids, evidence of pregnancy before

administration of products and abnormal results of paraclinical tests (leukocytopenia , leukocytosis , thrombocytopenia , anemia , hyperkalemia , hypokalemia , hypernatremia , hyponatremia) .

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **12**

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

Research Deputy of Tehran Medical University

Street address

6 Floor , Central Office of University , Keshavarz Blv.

City

Tehran

Postal code

Approval date

2012-01-03, 1390/10/13

Ethics committee reference number

2200/130/90/ص

Health conditions studied

1

Description of health condition studied

Glabellar Facial lines

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Occurrence any local and systemic adverse effects

Timepoint

At day 3, 7, 14, 30, 60, 90 and 120 post-injection

Method of measurement

Clinical examination , blood and urine analysis

2

Description

Subject Global Assessment of Change (SGA)

Timepoint

At days 0 , 3 , 7 , 14 , 30 , 60 and 120 Post-injection

Method of measurement

Subject's global assessment

3

Description

Rating of glabellar line severity at maximum frown

Timepoint

At days 3, 7, 14 and 30 post-injection

Method of measurement

Rating of glabellar line severity

Secondary outcomes

1

Description

Rating of glabellar line severity at rest

Timepoint

At day 30 post-injection

Method of measurement

Rating of glabellar line severity

Intervention groups

1

Description

Masport® 500 unit vial manufactured by Masoondarou Co. Each vial contain 500 unit botulinum type a toxin , 0.5 mg human albumin and 2.5 mg lactose . The dose of this product for treatment of glabellar lines in this study is 10 unit for injection in 5 sites for first 3 volunteer , 20 unit for second 3 volunteer , 40 unit for thirth 3 volunteer and 60 unit for fourth 3 volunteer at 14 days intervals , respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Amir Hooshang Ehsani

Street address

Vahdat islami Avenue , Vahdat islami square

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Masoondarou Co.

Full name of responsible person

Dr Naser Mohammadpour

Street address

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

Research Deputy of Ministry of Health

Full name of responsible person

Dr. Mostafa Ghaneie

Street address

Azadi Avenue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Deputy of Ministry of Health

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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Full name of responsible person

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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