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)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Masoondarou Biopharmaceutical Co. & Research Deuty of Ministry of Health, Islamic Repubic 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 , respectivvely.

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
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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