

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effects and side effects of Dysport and Masport in patients referred to the ultra-specialized oculoplasty clinic of Farabi Hospital in 1402

Protocol summary

Study aim

Comparing the effects and side effects of two drugs, Dysport and Masport

Design

A clinical trial with 2 random groups, Masport and Dysport, double-blind, randomized, phase 2 on 160 patients.

Settings and conduct

This study will be conducted in the oculoplastic clinic of Farabi Hospital in Tehran, Iran. The study will be conducted in a double-blind manner, and none of the doctors and patients will know the type of injected drug. Before and after the injection, the questionnaire is completed by the patients and the relevant doctor. Before and after the injection, the faces of the patients are photographed while laughing, frowning, and indifference. The patients are followed up at intervals of 2 weeks, 2 months, and 4 months after the injection.

Participants/Inclusion and exclusion criteria

1-Physical and mental health of the participants 2- Decision-making power and completely voluntary participation in the study 3- Allowed age range 27-57 4- Confirmation of the need for injection by the doctor and the candidate for Botox injection 5-Candidates for oculoplasties

Intervention groups

Patients in two intervention groups are included in the study, 80 people will be injected with masport drug and 80 people will be injected with dysport drug. The study was double-blind and none of the patients and related doctors knew about the type of medicine.

Main outcome variables

1- Investigating the effect of two drugs in the same doses in removing and reducing the depth of wrinkles in patients 2- Examining the short-acting and long-acting side effects of both drugs, including inflammation, redness, and drooping of the eyelids. 3- Checking the

shelf life of two drugs 4- Checking the need for re-injection and restoration of two drugs at intervals of 2 weeks, 2 months and 4 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230727058942N1**

Registration date: **2023-12-18, 1402/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-18, 1402/09/27**

Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Ghazal Ghochani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 5248

Email address

gghochani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-27, 1402/06/05

Expected recruitment end date

2024-02-24, 1402/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects and side effects of Dysport and Masport in patients referred to the ultra-specialized oculoplasty clinic of Farabi Hospital in 1402

Public title

comparison between masport and dysport in facial botox

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Physical and mental health The ability to make decisions regarding voluntary participation in the study Permissible age range in study (27-54 years old) Botox injection candidate in the studied areas

Exclusion criteria:

History of heavy surgeries and any type of fracture in any part of the face History of stroke and facial paralysis

Age

From **27 years** old to **57 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed using a stratified permuted block randomization method with random block lengths (2, 4, 6). After screening, patients will be randomly assigned to groups A and B in a 1:1 ratio to receive Dysport or Masport injections. Stratification variables, including age and gender, will be determined as follows: ARMS (RATIOS: 1:1): * A * B STRATIFY: Yes TOTAL STRATA: 4 STRATIFICATION VARIABLES: 1) Sex: * male * female 2) age: * <40 * >40 For this purpose, a randomization program was written in R software with the help of the center's biostatistician, and the randomization output was produced as an Excel file. Patients, researchers, and site personnel (except pharmacists) are blinded to the type of injectable drug and will remain so until the end of the follow-up period and analysis of the study data.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, which is a kind of double-blind study, all participating patients and doctors involved, including the

relevant professor who is responsible for the injection and the relevant resident who is responsible for coordinating and writing articles and theses, as well as the nurse related to The design is all kept blind during the design and it is an injectable drug type (Mesport or Dysport brand) do not know. Injection vials are prepared in completely identical and similar syringes by the relevant person and brought to the hospital.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Farabi Ophthalmology Hospital, Qazvin Square, Tehran

City

tehran

Province

Tehran

Postal code

1336616351

Approval date

2023-07-22, 1402/04/31

Ethics committee reference number

IR.TUMS.FARABIH.REC.1402.015

Health conditions studied**1****Description of health condition studied**

Investigating the therapeutic effects of two drugs, MASPORT and DYSPORT, on wrinkles around the eyes. forehead

ICD-10 code

H00-H06

ICD-10 code description

بررسی اختلالات کاسه چشم و پلک ها

Primary outcomes**1****Description**

1- To investigate the effect of two drugs in the same doses in removing and reducing the depth of wrinkles in patients.

Timepoint

At the beginning of the study, the day of injection, 14 days later, 2 months later and 4 months after injection

Method of measurement

A questionnaire prepared and completed by the doctor and the patient and photos taken of the target areas before and after the injection, which examines the function of the frown muscles and forehead muscles.

2

Description

2- Examining the short-acting and long-acting side effects of both drugs, including inflammation, redness, and drooping of the eyelids.

Timepoint

At the beginning of the study, the day of injection, 14 days later, 2 months later and 4 months after injection

Method of measurement

A questionnaire prepared and completed by the doctor and the patient and photos taken of the target areas before and after the injection, which examines the function of the frown muscles and forehead muscles.

3

Description

3- Checking the shelf life of two drugs

Timepoint

At the beginning of the study, the day of injection, 14 days later, 2 months later and 4 months after injection

Method of measurement

A questionnaire prepared and completed by the doctor and the patient and photos taken of the target areas before and after the injection, which examines the function of the frown muscles and forehead muscles.

4

Description

4- Checking the need for re-injection and restoration of two drugs at intervals of 2 weeks, 2 months and 4 months.

Timepoint

At the beginning of the study, the day of injection, 14 days later, 2 months later and 4 months after injection

Method of measurement

A questionnaire prepared and completed by the doctor and the patient and photos taken of the target areas before and after the injection, which examines the function of the frown muscles and forehead muscles.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: under MASPORT injection. Each person is injected with 110 units of medicine that contains the chemical composition

of botulinum toxin and is manufactured by Masoun Daru pharmaceutical company with the permission of the Ministry of Health in Iran. 500 vials of this medicine are diluted with 2.6 cc of distilled water and placed in an anonymous and unmarked vial for the validity of randomization, and in each person, 50 units of the forehead area, 30 units of the frown line, and 30 units of the wrinkles around the eyes are injected with a syringe. In this study, 1 injection was performed.

Category

Treatment - Drugs

2

Description

Control group: intervention group 2: they are subjected to DYSPORT injection. Each person is injected with 110 units of medicine that contains the chemical composition of botulinum toxin and is available in the country under the brand name DYSPORT with the official license of the Ministry of Health as an import made in Italy or France. 500 vials of this medicine are diluted with 2.6 cc of distilled water and placed in an anonymous and unspecified vial for the validity of randomization, and 50 units of the forehead area, 30 units of the frown line, and 30 units of the wrinkles around the eyes are injected with an insulin syringe. In this study, 1 injection was performed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi eye hospital

Full name of responsible person

Ghazal ghochani

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Farabi Ophthalmology Hospital, Qazvin Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

Street address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Masoun Daro Company

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ghazal ghochani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Latest degree

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Person responsible for updating data

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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