Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

A Double blind, Randomized, Comparative study of the Efficacy and Safety of Botulinum Toxin type A Masport with commercial brand Dysport in the treatment of Primary Axillary Hyperhidrosis

Protocol summary

Study aim

Evaluation of the efficacy and Safety of botulinum toxin type- A Masport compared to Dysport in the treatment of primary axillary hyperhidrosis.

Design

A double blind, randomized, phase 4 clinical trial with a parallel control group on 15 patients. The lottery function will be used for the randomization.

Settings and conduct

This is a double blind, controlled clinical trial that will be conduct on patients who come to Razi dermatology Hospital with the complain of hyperhidrosis (HH). Diagnosis of HH will be done by using Gravimetry test. Before and after the treatment process, patients will answer to a questionnaire that qualitatively determines the severity of their HH (4 point scale). in this way, by 1 or 2 point decrease in 4 point scale of sweating intensity, 50% and 80% of treatment response will be determined respectively. Gravimetry test results will be recorded at day 0, 2 weeks, 3 months and 6 months after injection. patients will be monitored for adverse effects during the study. the botulinum toxin vials will be covered in a way that neither the doctor nor the patient will know the brand of drugs used in each axilla.

Participants/Inclusion and exclusion criteria

Inclusion criteria; adults aged between 18 and 65 who have a sweating rate of 50 mg per minute or higher. Exclusion criteria; secondary Hyperhidrosis due to systemic problems, Pregnancy, Lactation, people who have taken Aminoglycosides in the last three weeks, people who have had botulinum toxin injection in the past year, people with Neuromuscellar diseases.

Intervention groups

The intervention will be done in parallel with the injection of 165 units test (Masport) and control (Dysport) drug divided in 20 points in each axilla.

Main outcome variables

The effectiveness of Masport in reducing sweating from two qualitative and quantitative aspects; The safety of Masport in the treatment of primary axillary Hyperhidrosis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220620055230N1**
Registration date: **2022-09-26, 1401/07/04**
Registration timing: **retrospective**

Last update: **2022-09-26, 1401/07/04**
Update count: **0**

Registration date

2022-09-26, 1401/07/04

Registrant information

Name

kamand hedayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2297 7901

Email address

kamandhedayat@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-09-08, 1401/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Double blind, Randomized, Comparative study of the Efficacy and Safety of Botulinum Toxin type A Masport with commercial brand Dysport in the treatment of Primary Axillary Hyperhidrosis

Public title

Investigation of the effect of Masport on Excessive Underarm Sweating

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged between 18 to 65 years who have a sweating rate of 50 mg per minute or higher.

Exclusion criteria:

secondary Hyperhidrosis due to systemic problems. Pregnancy Lactation people who have taken Aminoglycosides in the last three weeks. people who have had botulinum toxin injection in the past year. people with Neuromuscellar diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

In this study, each participant will receive both control and test drug in parallel in two axillae (one drug in each axilla)

Randomization (investigator's opinion)

Randomized

Randomization description

The Randomization process using lottery will be done for patients 1 to 15 by order of referral in such a way that a lot will be drown from the lots that have the name of drug and corresponding Axilla (for example Masport-Right).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study each participant will receive both control and test drug in parallel in two axilla (one drug in each axilla). The botulinum toxin vials of test and control group will be covered in a way that neither the doctor nor the patient will know the brand of drugs used in each axilla. The evaluation of treatment effectiveness will be done in 2 ways. Once with sweating measurement by the nurse who is not aware of the botulinum toxin brand used in each axilla and once according to the patient assessment regarding the amount of sweating, which is mentioned earlier, the patient has no knowledge of the botulinum toxin brand used in each axilla. Only the researcher who designed the study knows the type of botulinum toxin used in each axilla in each patient.

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

No. 69, Pasteur Ave

City

Tehran

Province

Tehran

Postal code

1316943551

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1312

Health conditions studied

1

Description of health condition studied

Primary Axillary Hyperhydrosis

ICD-10 code

L74.510

ICD-10 code description

Primary focal hyperhidrosis, axilla

Primary outcomes

1

Description

The score of sweating rate in the questionnaire of "Hyperhidrosis disease severity scale" by patients

Timepoint

scoring of the amount of sweating will be done on day 0 (before the stat of the study), 14, 90 and 180 days after botulinum toxin injection.

Method of measurement

The questionnaire "Hyperhidrosis disease severity scale".

2

Description
Sweating rate based on Gravimetry test
Timepoint
measurement of the sweating will be done on day 0 (before the stat of the study), 14, 90 and 180 days after botulinum toxin injection.
Method of measurement
Using a digital scale

3

Description
occurrence of the side effects, The time of onset and duration of the complication
Timepoint
Patients will be able to report occurrence of the side effects throughout the study, but they will be asked specifically on 14th, 90th and 180th after Botulinum Toxin injection.
Method of measurement
Statements of patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:All 15 participants in this study will be injected with 165 IU botulinum toxin type A Masport (each vial contains 500 IU of botulinum toxin type A that will be diluted with 3 cc normal saline) which is produced by Masoon Darou pharmaceutical company, Iran in one of their two axillae. This injection will be done once and participants will be evaluated during a period of 6 months after injection.
Category
Treatment - Drugs

2

Description
Control group: All 15 participants in this study will be injected with 165 units botulinum toxin type A Dysport (each vial contains 500 units of botulinum toxin type A that will be diluted with 3 cc normal saline) manufactured by Ipsen Company, England in one of their two axillae. This injection will be done once and participants will be evaluated during a period of 6 months after injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Amir Houshang Ehsani
Street address
Vahdat Eslami Ave
City
Tehran
Province
Tehran
Postal code
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Phone
+98 21 5563 0553
Fax
+98 21 5563 4461
Email
Razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Nasimi
Street address
Razi hospital., Vahdat Eslami Ave
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Fax
+98 21 5563 4461
Email
razihospital@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Masoon Darou Pharmaceutical 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
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Pasture Institute of Iran
Full name of responsible person
kamand Hedayat
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Documentation of randomization process, Documentation of the sweating intensity before and after treatment based on qualitative questionnaire of sweating interference with daily activities, Documentation of the sweating intensity before and after treatment based on quantitatively Gravimetry questionnaire can be requested after completing the study. The documentation related to the type of statistical analysis method and the corresponding codes of each of the two types of botulinum toxin can be requested after completing the study. The informed consent form, which will be available to the participants for signature on day zero, can be requested after completing the study. All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Access to the data will be after the results are published.
To whom data/document is available
the data will be accessible to all researchers.
Under which criteria data/document could be used
There is no problem using the data in other studies as

long as the source is mentioned.

From where data/document is obtainable

Kamand Hedayat kamandhedayat@yahoo.com Pasteur street, No 69, Pasteur Institute of Iran. tel: 66953311 -0098-21 fax: 66465132 -0098-21

What processes are involved for a request to access data/document

The researcher requests access to the data preferably through email and it will be send to him within a maximum of 10 days.

Comments