

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The evaluation of botulinum toxin efficacy on drooling of the patients referring to neurology department of Ahvaz Golestan hospital

Protocol summary

Summary

(1) Objectives: evaluation of botulinum toxin efficacy on drooling of the patients with neurologic diseases (2) Design: Single central, Phase 2 trial (3) Setting and conduct: injection of 60 unit dysport in each submandibular gland plus injection of 120 unit dysport in each parotid gland under guide of sonography. Injection is performed in 2 sites of each parotid gland and one site in each submandibular gland. For evaluation of drooling, we count number of used handkerchief in one day. The handkerchiefs are given to the patient in 10th packages and then evaluated before injection and 6 and 12 weeks after injection (4) Participants including major eligibility criteria: 10 patients. Major inclusion criteria: any over 10 y/o patient with any neurologic disorder that suffers from sialorrhea. Exclusion criteria: Any neuromuscular junction disease, pregnancy or lactation period, History of any salivary gland tumor or inflammatory disease, infection of injection site (5) Intervention: injection of 60 unit dysport in each submandibular gland plus injection of 120 unit dysport in each parotid gland under guide of sonography (6) main outcome measures: salivation volume

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110515289N1**

Registration date: **2013-12-19, 1392/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-19, 1392/09/28

Registrant information

Name

Mojtaba Khademiyan ghadikolaee

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3012

Email address

khademiyan.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of botulinum toxin efficacy on drooling of the patients referring to neurology department of Ahvaz Golestan hospital

Public title

The effect of botulinum toxin on decrease of sialorrhea in patients with neurologic disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: between 10-85 years old patient with any neurologic disorder that suffers from sialorrhea

Exclusion criteria: 1- Any neuromuscular junction disease

2-Pregnancy or lactation period 3-History of any salivary gland tumor or inflammatory disease 4-Infection of injection site

Age

From **10 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand St. Golestan Blv. Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

61357-15794

Approval date

2013-01-07, 1391/10/18

Ethics committee reference number

Eth-681

Health conditions studied

1

Description of health condition studied

Sialorrhea

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Severity of sialorrhea

Timepoint

Before injection-6 and 12 weeks after injection

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Dysport is an injection containing abobotulinumtoxinA (Botulinum toxin type A). AbobotulinumtoxinA is made from the bacteria that cause botulism. Dysport blocks the release of acetylcholine and a number of other neurotransmitters from synaptic vesicles. Inject of 120 unit dysport in each parotid gland and 60 unit dysport in each submandibular salivary gland.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Mojtaba Khademiyan Ghadikolaee, MD

Street address

Nosrat St. Golestan Blvd. Golestan hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mostafa Fegghi, MD

Street address

Esfand St. Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mojtaba khademiyan ghadikolaee, MD

Position

Resident of Neurology

Other areas of specialty/work

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Seyed Ehsan Mohamadianinejad, MD

Position

Assistant Professor

Other areas of specialty/work

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