Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effectiveness of botulinum toxin type A injection in reducing salivation and improving quality of life in patients with cerebral palsy

Protocol summary

Study aim
Determining the effect of botulinum toxin type A on reducing salivation and quality of life in patients with cerebral palsy in Imam Hossein Hospital, Isfahan

Design
Clinical trial in which the control group is patients before injection; non-blinded; non-random; About 30 patients

Settings and conduct
First, 500 units of botulinum toxin type A (Botox®, Masport, Iran) are diluted with 3 ml of normal saline. The child is placed in the supine position so that the head can be rotated to both sides, then in each of the parotid and submandibular glands 0.5 units per kilogram by an ENT specialist under ultrasound guide by a radiologist without anesthesia؛ Is injected. Needle number 25G is used for injection. These procedures are performed in the operating room of Imam Hossein Hospital in Isfahan.

Participants/Inclusion and exclusion criteria
Patients with cerebral palsy; Intensity score and salivation more than 4; No contraindication to injection; No receive systemic saliva-reducing drug and Botox injection in the previous three months; No recent maxillofacial surgery related to salivation

Intervention groups
Botox injection in parotid and submandibular glands in patients with cerebral palsy

Main outcome variables
Quality of life with Teacher drooling scale Severity of salivation with Drooling Frequency and Severity scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054868N1**
Registration date: **2022-09-22, 1401/06/31**
Registration timing: **retrospective**

Last update: **2022-09-22, 1401/06/31**
Update count: **0**

Registration date
2022-09-22, 1401/06/31

Registrant information

Name
Mohadese Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3778 5759

Email address
ghasemi.mhds@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-26, 1401/04/05

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of botulinum toxin type A injection in reducing salivation and improving quality of life in patients with cerebral palsy

Public title
The effect of botulinum toxin type A on reducing

salivation and quality of life in patients with cerebral palsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Affliction cerebral palsy Drooling score more than 4

Exclusion criteria:

Contraindications for injection of Botulinum toxin A Botulinum toxin type A injection in three month ago Perform recent maxillofacial surgery that may interfere with saliva production and flow Receive systemic medication to treat sialorrhea in the last three months

Age

From **1 year** old to **16 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Isfahan University of Medical Sciences

Street address

Level 2, Nomber 257, Alley 8 th , Erfan Street, Molana Street, Janbazan Street, Keshavarz Blvd

City

Isfahan

Province

Isfehan

Postal code

8174796149

Approval date

2022-01-24, 1400/11/04

Ethics committee reference number

IR.MUI.MED.REC.1400.774

Health conditions studied

1

Description of health condition studied

Cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

The amount and intensity of saliva secretion based on drooling frequency and severity score

Timepoint

drooling frequency and severity Score before injection, 2 weeks after injection, one month, 2 months, 4 months and 6 months after injection

Method of measurement

drooling frequency and severity Score

Secondary outcomes

1

Description

Quality of life score related to salivation based on a questionnaire

Timepoint

Before injection, 2 weeks after injection, one month, 2 months, 4 months and 6 months after injection

Method of measurement

Teacher drooling scale

Intervention groups

1

Description

Intervention group: For patients with cerebral palsy, first 500 units of botulinum toxin type A (Botox®, Masport, Iran) is diluted with 3 ml of normal saline. The child is placed in the supine position so that the head can rotate in both directions, then 0.5 units per kilogram of body weight are injected into each of the parotid and submandibular glands by an ENT specialist under an ultrasound guide by a radiologist without anesthesia. Needle number 25G is used for injection. This operation is performed in the operating room of the hospital.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Mohadeseh Ghasemi
Street address
Imam Hossein Hospital, Imam Khomeini Street
City
Isfahan
Province
Isfehan
Postal code
8195163318
Phone
+98 31 3386 6266
Email
emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansoor Siavash
Street address
Building No. 4,Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7898
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
20
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohadeseh Ghasemi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Level 2, Nomber 257,Alley 8 th , Erfan street, Molana street, Janbazan street, Keshavarz Blvd
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۷۹۶۱۴۹
Phone
+98 31 3778 5759
Email
ghasemi.mhd@gmai.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohadeseh Ghasemi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Level 2, Nomber 257, Alley 8 th , Erfan Street, Molana Street, Janbazan Street, Keshavarz Blvd
City
Isfahan
Province
Isfehan
Postal code
8174796149
Phone
+98 31 3778 5759
Email
ghasemi.mhds@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohadeseh Ghasemi
Position
Resident
Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Level 2, Nomber 257, Alley 8 th , Erfan Street, Molana Street, Janbazan Street, Keshavarz Blvd

City

Isfahan

Province

Isfehan

Postal code

8174796149

Phone

+98 31 3778 5759

Email

ghasemi.mhds@gmail.com

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