

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Botulinum toxin type A on reducing sialorrhea in patients with cerebral palsy in Akbar Children's Hospital

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of botulinum toxin type A on reducing sialorrhea in cerebral palsy patients in Akbar Children's Hospital

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Design

A single group study clinical trial, phase 2 on 20 patients and outcome assessment

Registrant information

Name

Mehrnaz Nazarirad

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

The present study is a clinical trial performed in Akbar Children's Hospital. Vial toxin botulinum A 30 to 50 units (less than 15 kg 30 units, between 15 to 25 kg 40 units and more than 25 kg 50 units) depending on the patient's weight is injected into the salivary glands by an ear, nose and throat specialist under an ultrasound guide.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Patients with cerebral palsy; between 4 and 16 years old; with a Frequency drooling scale score 4 and Severity and Teacher drooling scale more than 4 are included in this study. Patients with contraindications of botulinum toxin A injection; history of botulinum toxin A injection for at least the past 4 months are excluded from the study.

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Children with cerebral palsy Injection of botulinum toxin type A in the salivary glands of children with cerebral palsy

Main outcome variables

Outcomes associated with botulinum toxin injection (intensity and frequency of drooling) are assessed using Drooling Frequency or severity scale and teacher drooling scale before, 2 weeks, 1 month, 2 months, 4 months, 6 months and 9 months after injection.

Scientific title

The effect of Botulinum toxin type A on reducing sialorrhea in patients with cerebral palsy in Akbar Children's Hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053995N1**

Registration date: **2022-02-20, 1400/12/01**

Public title

The effect of Botulinum toxin type A on sialorrhea in patients with cerebral palsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients with cerebral palsy Drooling frequency scale 4 and severity and Teacher scale more than 4 Age between 4 and 16 years Consent of parents or legal guardians to enter the study

Exclusion criteria:

Contraindications of botulinum toxin A injection such as myasthenia gravis and Eaton-Lambert syndrome Botulinum toxin A injection for at least the last four months Receiving systemic medication to treat sialorrhea in the last three months Recent maxillofacial surgery that may interfere with saliva production and flow.

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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 Mashhad University of Medical Sciences

Street address

Akbar Children's Hospital., Kaveh Blvd., TV square

City

Mashhad

Province

Razavi Khorasan

Postal code

91778 99191

Approval date

2021-10-19, 1400/07/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.535

Health conditions studied

1

Description of health condition studied

cerebral palsy; sialorrhea

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Drooling frequency score based on Drooling frequency scale and Teacher drooling scale

Timepoint

Before intervention, 2 weeks, 1 month, 2 months, 4 months, 6 months and 9 months after botulinum toxin injection

Method of measurement

Drooling Frequency and Teacher drooling scale

2

Description

Drooling severity score based on Drooling severity scale and Teacher drooling scale

Timepoint

Before intervention, 2 weeks, 1 month, 2 months, 4 months, 6 months and 9 months after botulinum toxin injection

Method of measurement

Drooling Severity and Teacher drooling scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vial toxin botulinum type A (massport) diluted with 3.2 cc of normal saline and depending on the patient's weight in each salivary gland 30 to 50 units (less than 15 kg 30 units, between 15 to 25 kg 40 Units and more than 25 kg 50 units) are injected by an ear, nose and throat specialist under an ultrasound guide.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital
Full name of responsible person
Seyed Javad Sayedi
Street address
Akbar Children's Hospital., Kaveh Blvd., TV square
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Seyed Javad Sayedi
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Subspecialist
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
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
Mashhad University of Medical Sciences
Full name of responsible person

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
seyed Javad Sayedi
Position
Associate Professor of Pediatric Pulmonology
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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