

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Botulinum toxin injection in pediatric population affected by spastic neuropathic bladder resistant to medical therapy

Protocol summary

Study aim

This study is going to measure the effect of botulinum injection in children with neurogenic bladder for first time in iran.

Design

Clinical trial without control group

Settings and conduct

Patients who have the inclusion criteria, will be assessed by primary urodynamic study after registering the demographic index. Consequently, endoscopic Botox injection will be done by a single surgeon under general anesthesia in Operating room. Secondary urodynamic study will be done after 3 months and the results will be compared.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children ,affected with Spastic Neurogenic Bladder, who are referred to Mofid Sub specialty Children's Hospital ,and are under treatment with clean intermittent catheterization, and maximal medical therapy by anticholinergic drugs ,and revealed drug related complications ,or resistance Exclusion Criteria: Patients who have been undergone prior bladder augmentation surgery, Patients who their parents or their legal guardian don't accept their study enrollment

Intervention groups

Botulinum injection is going to be done under the general anesthesia with rigid cystoscope and endoscopic needle for all of the patients. To modify the botulinum concentration it will be diluted with normal saline and in order to inject accurately a small amount of methylene blue will be used. Approximately 10 unit of botulinum toxin will be injected in anterior and posterior detrusor wall without injection into the trigon . Administered botulinum dosage will be 10 U/kg with the maximum dose of 300 units. Manufacturer company: Ipsen Biopharm Ltd,UK

Main outcome variables

Bladder capacity after injection, Hours not demanding diaper change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181124041743N1**

Registration date: **2019-02-12, 1397/11/23**

Registration timing: **retrospective**

Last update: **2019-02-12, 1397/11/23**

Update count: **0**

Registration date

2019-02-12, 1397/11/23

Registrant information

Name

Saran Lotfollahzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 6122

Email address

s.lotfollahzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-30, 1397/09/09

Expected recruitment end date

2019-01-15, 1397/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Botulinum toxin injection in pediatric population affected by spastic neuropathic bladder resistant to medical therapy

Public title

Botulinum toxin injection in pediatric population with spastic neuropathic bladder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under the age of 18 Affected with Spastic Neurogenic Bladder Refer to Mofid Children's Hospital Under treatment with Clean Intermittent Catheterization Under treatment with maximal medical therapy with anti-cholinergic drugs Reveal anti-cholinergic drugs related complications Reveal anti-cholinergic drugs resistance

Exclusion criteria:

Patients who have been undergone prior bladder augmentation surgery Patients that their parents or their legal guardian don't accept their study enrollment

Age

To 18 years old

Gender

Both

Phase

2-3

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 shahid beheshti university of medical sciences

Street address

Koudakyar str, daneshjou blv

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.SBMU.MSP.REC.1397.593

Health conditions studied

1

Description of health condition studied

Neurogenic bladder

ICD-10 code

N31.9

ICD-10 code description

Neuromuscular dysfunction of bladder, unspecified

2

Description of health condition studied

Neurogenic bladder dysfunction due to cauda equina syndrom

ICD-10 code

G95.8

ICD-10 code description

Other specified diseases of spinal cord

Primary outcomes

1

Description

Bladder capacity after injection.

Timepoint

Before intervention and 3 months after that

Method of measurement

Mofid children Hospital urodynamic measurement device ,model DELPHIS IP, MODEL: 94_RO1P_BT;Manufactured by LABORIE MEDICAL TECHNOLOGIES.

2

Description

Hours of not demanding diaper change

Timepoint

Before and 3 months after Botox injection

Method of measurement

Interview with parents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who have the inclusion criteria to enrol the study,first will undergo primary urodynamic study with DELPHIS IP,MODEL 94_RO1P_BT

manufactured by LABORIE MEDICAL TECHNOLOGIES and interview with parents. Bladder volume and number of hours not demanding diaper change will be registered. After that Botox manufactured by Ipsen Biopharm Ltd UK with the amount of 10u/kg and maximal dose of 300units will be injected in Operating room under general anesthesia with rigid cystoscope by one surgeon. Site of injection is in detrusor muscles along with anterior and posterior far from trigon. Three months later, repeated urodynamic study with the same primary device and interview with parents will be done and bladder volume and hours not demanding diaper change will be recorded, respectively.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid Children Hospital

Full name of responsible person

Saran Lotfollahzadeh

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saran Lotfollahzadeh

Position

Pediatric surgery fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Position

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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