

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluation of the effect of extracorporeal shockwave therapy after botulinum toxin injection on cuff muscle spasticity improvement in patients with multiple sclerosis

#### Protocol summary

##### Study aim

Determining the effect of extracorporeal shock wave therapy after botulinum toxin injection on cuff muscle spasticity improvement in patients with multiple sclerosis

##### Design

A randomized, single-blinding clinical trial, with the parallel groups, Phase 2 on 20 patients

##### Settings and conduct

In this randomized single-blind clinical trial study, 20 eligible patients referred to Alzahra and Kashani hospitals in Isfahan will be included in the study and will be randomly divided into two groups. For patients in the first group, only botulinum toxin is injected according to the standard protocol. Patients in the second group are treated with extracorporeal shockwave after botulinum toxin injection. Then the spasticity score and the pain score due to spasticity are evaluated and compared between the two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included a definitive diagnosis of multiple sclerosis based on the opinion of a neurologist, presence of spasticity in the cuff muscles (based on a score of more than 1 on the modified Ashworth scale (MAS), and consent to participate in the study. Exclusion criteria include having a cognitive impairment (in advanced stages of the disease), having myopathy or peripheral nerve disease, having a pacemaker, pregnancy, pre-injection of botulinum toxin during the last 6 months, having cuff muscle atrophy, having coagulation disorders, have a history of surgery or previous fractures at the site of muscle spasticity.

##### Intervention groups

Control group: In this group, only botulinum toxin injection with BTX-A was performed for the patient under the standard protocol. For this purpose, 100-200 mU of Botox type A, Dysport is used. spasticity is injected. Intervention group: In this group, after injecting

botulinum toxin, extracorporeal shock wave therapy is performed.

##### Main outcome variables

Spasticity score; Pain score due to spasticity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N41**

Registration date: **2021-09-27, 1400/07/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-09-27, 1400/07/05**

Update count: **0**

##### Registration date

2021-09-27, 1400/07/05

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2021-12-21, 1400/09/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effect of extracorporeal shockwave therapy after botulinum toxin injection on cuff muscle spasticity improvement in patients with multiple sclerosis

**Public title**  
Evaluation of the effect of extracorporeal shockwave therapy after botulinum toxin injection on cuff muscle spasticity improvement

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Definitive diagnosis of multiple sclerosis based on the opinion of a neurologist Presence of spasticity in the cuff muscles (based on a score of more than 1 on the modified Ashworth scale (MAS) consent to participate in the study  
**Exclusion criteria:**  
Having cognitive disorders (in advanced stages of the disease) Having myopathy or peripheral nerve disease Having a pace maker Pregnancy Pre-injection of botulinum toxin during the last 6 months Having cuff muscle atrophy Having coagulation disorders History of previous surgery or fracture at the site of spastic muscles

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: 20

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, eligible patients will likely be selected sequentially. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Due to the nature of the current study, the researcher is aware of the type of intervention in each of the two groups, but the patient and the evaluator (data collector)

are not aware of the type of surgery in each group

**Placebo**  
Not used

**Assignment**  
Parallel

**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**  
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8179964167

**Approval date**  
2019-10-09, 1398/07/17

**Ethics committee reference number**  
IR.MUI.MED.REC.1398.351

## Health conditions studied

**1**

**Description of health condition studied**  
Multiple sclerosis

**ICD-10 code**  
G35

**ICD-10 code description**  
Multiple sclerosis

## Primary outcomes

**1**

**Description**  
Pain

**Timepoint**  
Before, immediately, 2 weeks and 8 weeks after the intervention

**Method of measurement**  
Visual Analogue Scale (VAS)

**2**

**Description**  
Spasticity score

**Timepoint**  
Before, immediately, 2 weeks, and 8 weeks after the

intervention

#### Method of measurement

Modified Ashworth's Scale (MAS)

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Control group: In this group, only botulinum toxin injection with BTX-A was performed for the patient under the standard protocol, for this purpose, 100-200 mU of Botox type A, Dysport is used. This injection is performed in the medial and lateral heads of the cuff muscle based on the severity of the spasticity.

##### Category

Treatment - Drugs

#### 2

##### Description

Intervention group: In this group, after injection of botulinum toxin with BTX-A according to the standard protocol, it is treated with extracorporeal shock wave therapy. For this purpose, radial energy is used with an intensity of 4 times and the its frequency is 8 Hz. The number of shocks is 2000 shocks on the gastrocnemius muscles, 600 shocks on the soleus muscle and 200 shocks on the Achilles tendon. The number of sessions is 5 sessions once a week. The device used for ESWT is Nortz Medical- Duolith SD1.

##### Category

Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Al-Zahra Hospital

###### Full name of responsible person

Shila Haghghat

###### Street address

Department of Physical Medicine and Rehabilitation,  
Al-Zahra Hospita, Sefeh Blvd., Tohid Street

###### City

Isfahan

###### Province

Isfahan

###### Postal code

8174675731

###### Phone

+98 31 3620 2020

###### Email

Haghghatshila@gmail.com

#### 2

##### Recruitment center

###### Name of recruitment center

Kashani Hospital

###### Full name of responsible person

Shila Haghghat

###### Street address

Department of Physical Medicine and Rehabilitation,  
Kashani Hospital, Kashani Street.

###### City

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###### Postal code

8183983434

###### Phone

+98 31 3233 0091

###### Email

Haghghatshila@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Esfahan University of Medical Sciences

###### Full name of responsible person

Shaghayegh Haghjooy Javanmard

###### Street address

Vice Chancellor for Research, School of Medicine,  
Hezar Jarib Street, Isfahan.

###### City

Isfahan

###### Province

Isfahan

###### Postal code

8174673461

###### Phone

+98 31 3668 8597

###### Email

dean@med.mui.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shila Haghighat

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Department of Physical Medicine and Rehabilitation,  
Al-Zahra Hospita, Sefeh Blvd., Tohid Street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Marjan Ghasri

**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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Marjaghasri25@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shila Haghighat

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Department of Physical Medicine and Rehabilitation,  
Al-Zahra Hospita, Sefeh Blvd., Tohid Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available