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: IIn 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)

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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

Isfehan

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 Haghighat

Street address

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

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2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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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