Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comprasion of efficacy of Drug therapy(Solifenacin Succinate) and physiotherapy(Stimulation of Posterior Tibialis Nerve) on treatment of overactive Bladder and quality of life in Patients with Multiple Sclerosis

Protocol summary

Study aim
Comprasion of efficacy of Drug therapy and Physiotherapy on treatment of overactive Bladder and quality of life in Patients with Multiple Sclerosis

Design
Clinical trial with two parallel groups, Single blind, Randomized, Phase 2 and performed on 75 Patients. Randomization using software and random block method in which two patients are randomly assigned in each block and generated A random sequence of code will occur

Settings and conduct
Ahvaz MS center

Participants/Inclusion and exclusion criteria
Inclusion criteria are: Have a minimum score of 3 in the actionable questionnaire to confirm neurogenic overactive Bladder No infection in the Urinary tract At least 1 month has passed since the onset of symptoms of overactive bladder disorder EDSS scale (severity of degree of disability) 1 to 5.5 Exclusion criteria are: Pregnant women and those who want to get pregnant within the next year Heart problems (such as Heart failure, etc.) Having diabetes and neurological diseases such as Parkinson's History of Electrotherapy treatment in the lower Limbs and lower Back and history of Pelvic floor Muscle Physiotherapy during a recent month Having a Heart pacemaker and a Prosthesis in the Leg

Intervention groups
All patients will continue their treatment regimen as before and for patients in the first group of sulifenacin drug therapy is first prescribed at a dose of 5 mg daily for 4 weeks and then increase the dose if the patient tolerates to 10 mg per day (5 mg). Twice a day) and lasts up to 8 to 12 weeks. For patients in the second group, physiotherapy will be performed by posterior tibialis nerve stimulation. The number of posterior tibial nerve stimulation sessions is 12 sessions in 12 weeks (one session per week) and duration. Each session will be 30 minutes.

Main outcome variables
Severity of urinary incontinence, urinary incontinence score, quality of life

General information

Reason for update

Acronym
Ms

IRCT registration information
IRCT registration number: **IRCT20210207050277N1**
Registration date: **2021-03-13, 1399/12/23**
Registration timing: **prospective**

Last update: **2021-03-13, 1399/12/23**
Update count: **0**

Registration date
2021-03-13, 1399/12/23

Registrant information

Name
Mohammad Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3374 3012

Email address
jafari.mo@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comprasion of efficacy of Drug therapy(Solifenacin Succinate) and physiotherapy(Stimulation of Posterior Tibialis Nerve) on treatment of overactive Bladder and quality of life in Patients with Multiple Sclerosis

Public title

The effect of Drug therapy on the treatment of overactive Bladder in Multiple Sclerosis, The effect of Physiotherapy on the treatment of overactive Bladder in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No infection in the Urinary tract Have a minimum score of 3 in the Actionable questionnaire to confirm Neurogenic overactive Bladder Urinary incontinence that may or may not be accompanied by urgent Urinary incontinence At least 1 month has passed since the onset of symptoms of overactiveBladder disorder At least one month has passed since the last MS attack EDSS scale (severity of degree of disability) 1 to 5.5

Exclusion criteria:

Pregnant Women and those who want to get Pregnant within the next year Allergy to the Drug Sulifenacin such as Angioedema Heart problems (such as Heart failure) Have a history of surgery to treat Urinary incontinence or other Urinary tract surgeries Having stress Urinary incontinence Having Diabetes and Neurological diseases such as Parkinson's History of Anticholinergic Drug therapy for the treatment of overactive Bladder during the last month History of Electrotherapy treatment in the lower limbs and lower back and history of Pelvic floor Muscle Physiotherapy during a recent month Having a Heart Pacemaker and a Prosthesis in the leg Having a lesion at the site of Electrical stimulation of the Posterior Tibial Nerve

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random block method, both people are randomly assigned to one of the two groups with the help of random codes generated. The size of the blocks is considered to be equal to 2, and inside each block, two random codes, one for group one and the other for group 2, are generated randomly. This is done with the help of random allocation https://www.sealedenvelope.com done.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single blind study, Participants and Outcome assessors are aware of the type of study, but Researchers and Data analyzer are not aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Department of Neurology, Golestan Hospital, Farvardin Street, Golestan

City

Ahvaz

Province

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Postal code

61357-15794

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.127

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

2

Description of health condition studied

Overactive Bladder Disorder

ICD-10 code

N32

ICD-10 code description

Other disorders of bladder

Primary outcomes

1

Description

Severity of Urinary Symptoms

Timepoint

Evaluation of urinary symptoms at the beginning of the study (before the intervention) and 4, 8 and 12 weeks after the intervention

Method of measurement

International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB)

2

Description

Urinary Incontinence

Timepoint

Evaluation of urinary incontinence at the beginning of the study (before the intervention) and 4, 8 and 12 weeks after the intervention

Method of measurement

International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form(ICIQ-UI SF)

Secondary outcomes

1

Description

Quality Of Life

Timepoint

Evaluation of Quality of life at the beginning of the study (before the intervention) and 4, 8 and 12 weeks after the intervention

Method of measurement

Multiple Sclerosis Quality of Life Questionnaire (MSQOL-54)

Intervention groups

1

Description

First Intervention group: Drug treatment The oral tablet of Sulifenacin succinate 5 mg under the brand name Vsol (Abidi Company) is used. It was developed in 2004 and is one of the antimuscarinic drugs that works by reducing bladder contractions. It is initially given at a dose of 5 mg daily for 4 weeks. Then increase the dose to 10 mg per day (5 mg twice daily) if the patient tolerates and lasts for 8 to 12 weeks.

Category

Treatment - Drugs

2

Description

Second Intervention group: Electrical stimulation of the posterior tibial nerve using a dual-channel x733 stimulator device with a model of 1396 and made in Iran will be applied. The current characteristics used will be as follows: intensity 0.5 to 10 mA, frequency 20 Hz, pulse length 200 microseconds.However, the intensity of the stimulation will increase to the threshold of motor nerve stimulation, which is characterized by flexion of the first toe. So far, no side effects have been reported on superficial electrical stimulation of the posterior tibial nerve. For electrical stimulation, the negative electrode (cathode) is placed behind the inner ankle and the positive electrode (anode) is 10 cm above the cathode. The number of posterior tibial nerve stimulation sessions will be 12 sessions in 12 weeks (one session per week) and the duration of each session will be 30 minutes.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Mohammad Jafari

Street address

Multiple Sclerosis Association, Golestan Hospital, Farvardin Street, Golestan

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dr.mohammadjafari1368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

مهدی احمدی مقدم

Street address

شهر دانشگاهی، معاونت تحقیقات و فناوری دانشگاه علوم پزشکی و خدمات بهداشتی درمانی جندی شاپور اهواز

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research@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Jafari

Position
Neurology resident

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

Contact

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Full name of responsible person
Mohammad Jafari

Position
Neurology resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After defending the dissertation and approval by Ahwaz

University of Medical Sciences, the collected data (after identifying the participants) will be fully available to researchers and patients.

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

If requested, the results will be available to other researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The information of this trial will be provided to researchers and patients with the aim of improving the quality of life of patients with multiple sclerosis.

From where data/document is obtainable

Receiving documents will be possible by sending an email to the person in charge of the update.

What processes are involved for a request to access data/document

Documents will be emailed over a ten-day period.

Comments