Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison study between the effect of amantadine and acupuncture in relieving fatigue in multiple sclerosis patients (randomized controlled trial)

Protocol summary

Study aim

Main purpose: Comparison of acupuncture and oral amantadine in relieving fatigue in patients with MS Exclusive purposes: 1- Evaluation of acupuncture as a treatment in relieving MS induced fatigue 2- Determine the amount of fatigue before and after acupuncture treatment 3- Determine the amount of fatigue before and after amantadine treatment 4- Determine quality of life improvement before and after acupuncture and amantadine treatment 5- Comparison of fatigue and quality of life improvement after acupuncture and amantadine treatment Practical purpose: To determine a treatment method with less side effects and more effectiveness than the existing drug to reduce fatigue in patients with MS

Design

Clinical trial with control group, parallel groups, double-blinded (analyst and questioner), randomized by block randomization through sealed envelope site, phase 3 on 60 patients

Settings and conduct

Two groups of 30 people, control group of oral amantadine 100 mg twice a day for 2 months, acupuncture intervention group in the desired areas 10 30 minutes sessions, three times a week, evaluation of fatigue and QoL before, after and 2 months after treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definite or possible MS with fatigue; Patients who have been suffering from MS induced fatigue for more than 6 months and an FSS score greater than 30, age range 18 to 50 years, no use of other anti-fatigue drugs except amantadine in the control group. Exclusion criteria: Probable MS, pregnant and lactating women, concurrent trauma, vitamin D and calcium deficiency, chronic metabolic and other diseases, coagulation disorders, smoking, dissatisfaction to continue treatment, death

Intervention groups

Acupuncture group, 10 sessions, three times a week, each session lasts for 30 minuets Amantadine-treated group, 100 mg BID for 2 months

Main outcome variables

fatigue, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210718051931N1**
Registration date: **2022-04-30, 1401/02/10**
Registration timing: **prospective**

Last update: **2022-04-30, 1401/02/10**
Update count: **0**

Registration date

2022-04-30, 1401/02/10

Registrant information

Name
Nasim Fazeli
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3670 0310
Email address
nasim.fazeli92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-23, 1401/03/02

Expected recruitment end date
2022-09-24, 1401/07/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison study between the effect of amantadine and acupuncture in relieving fatigue in multiple sclerosis patients (randomized controlled trial)

Public title
Effect of acupuncture in relieving fatigue of multiple sclerosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with definite or possible multiple sclerosis and suffer from fatigue Patients suffering from fatigue of multiple sclerosis for more than 6 months and confirmed with FSS score more than 30 Age range between 18-50 Not consuming any other fatigue relieving drugs except amantadine in control group
Exclusion criteria:
Probable cases of multiple sclerosis Pregnancy- lactating Acute fracture or trauma Patients with other chronic disease Patients with coagulation disorders Tobacco products use Refuse to continue the treatment Death
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization, 6 blocks performed by sealed envelope site by a statistician. Based on the presented list, which includes a random sequence of letters A and B, eligible patients are included in the list in groups A and B, respectively. Group A then receives control treatment and group B receives intervention treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients fatigue status is determined with some questionnaires before and after the treatment, the person who assesses these questionnaires doesn't know about patients treatment group, also data analyzer doesn't know about patients' treatment group
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand Blvd
City
Shiraz
Province
Fars
Postal code
7134844110
Approval date
2021-07-18, 1400/04/27
Ethics committee reference number
IR.SUMS.MED.REC.1400.209

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
fatigue with FSS more than 30, quality of life improvement with SF-36
Timepoint
before treatment, immediately after treatment, 2 months post treatment
Method of measurement
FSS, SF-36 questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group is treated with 10 sessions of acupuncture by the researcher physician. The patient is lying on his side and lying down in a relaxed environment. After topical application with an alcohol swab, 14 sterile needle size 0.25*25mm manufactured by Huan-Qiu company placed on the desired points (on the head, neck, back and legs) obtained by various studies and clinical experience, patients lie still for 30 minutes, then the needles are taken out by the researcher physician. Number of sessions per week: 3 sessions. Before the sessions begin, patients are given the necessary training to improve bruising and possible pain.

Category

Treatment - Devices

2

Description

Control group: 120 capsules of amantadine hydrochloride 100 mg, used twice a day for 2 months. One capsule in the morning after breakfast and one capsule in the afternoon after lunch with plenty of water, drug manufacturer: Fatek Shimi Pars Semnan - Iran

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza clinic
Full name of responsible person
Nasim Fazeli, Maryam Poursadeghfard
Street address
Zand street, Namazi Square, Imam Reza clinic
City
Shiraz
Province
Fars
Postal code
8168673731
Phone
+98 31 3670 0310
Email
nasim.fazeli92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Zand St., the central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
7194684334
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

60

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
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadjavad Hadianfard
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Zand St., Central Building of Shiraz Medical Science
City
Shiraz
Province
Fars
Postal code
7194684334
Phone
+98 71 3628 6418
Email
hadianj@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadjavad Hadianfard

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Zand St., Central Building of Shiraz Medical Sciences
City
Shiraz
Province
Fars
Postal code
7194684334
Phone
+98 71 3628 6418
Email
hadianj@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadjavad Hadianfard
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Zand St., Central Building of Shiraz Medical Sciences
City
Shiraz
Province
Fars
Postal code
71946-84334
Phone
+98 71 3628 6418
Email
hadianj@sums.ac.ir

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Age and sex of patients, type of medication used for MS Questionnaires related to fatigue and general patient function before and after the intervention Informed consent form Statistical results
When the data will become available and for how long
one year after result publication
To whom data/document is available
All physicians and medical researchers
Under which criteria data/document could be used
To use the results in other studies and for medical purposes
From where data/document is obtainable
Correspondence with Dr. Mohammadjavad Hadianfard via email hadianj@sums.ac.ir
What processes are involved for a request to access data/document
Send an email and provide the relevant ID card
Comments