Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Acupuncture Treatment with Routine Treatment on Fatigue among Patients with Multiple Sclerosis

Protocol summary

Study aim
This study is designed to investigate the clinical effectiveness of acupuncture combined with Interferon β-1a and Amantadine compared to IFN-β-1a and Amantadine alone on fatigue and quality of life of patients with relapsing-remitting multiple sclerosis in remission stage of disease.

Design
A randomized controlled parallel group trial on 60 patients with equal randomization (1:1 ratio) by Excel Rand function.

Settings and conduct
Study location: Heravi Clinic; School of Persian Medicine; Tehran University of Medical Sciences. Study Participants: The patients are recruited from Iran multiple sclerosis (MS) society in collaboration with MS Research Institute of Sina Hospital. In this study blinding is not applied.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 18 years old and above; with relapsing-remitting multiple sclerosis; in remission stage of disease; fatigue severity scale greater than 4. Non-inclusion criteria: History of other major primary disease (fatigue caused by a severe or malignant disease); acute relapse or corticosteroid therapy in the last 30 days before inclusion

Intervention groups
Intervention group: Acupuncture combined with Interferon β-1a (immunomodulator) and Amantadine (a medication used for fatigue in multiple sclerosis patients) Control group: Only medications

Main outcome variables
Fatigue severity scale; quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180914041035N2**
Registration date: **2021-09-19, 1400/06/28**
Registration timing: **prospective**

Last update: **2021-09-19, 1400/06/28**
Update count: **0**

Registration date
2021-09-19, 1400/06/28

Registrant information

Name
Amir Hooman Kazemi

Name of organization / entity

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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
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Acupuncture Treatment with Routine Treatment on Fatigue among Patients with Multiple Sclerosis

Public title

Acupuncture effect in MS Associated Fatigue

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple sclerosis patients Relapsing remitting type In remission stage of disease Confirmed by a neurologist Suffer from fatigue severity scale greater than or equal to 4 Age of 18 years old and above Signing the written informed consent for participating in the study

Exclusion criteria:

History of other major primary disease (fatigue caused by a severe or malignant disease) Acute relapse or corticosteroid therapy in the last 30 days before study Cognitive impairment and inability of cooperation Using any herbal or other alternative treatments Pregnancy or breastfeeding

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized equally to intervention and control groups by simple individualized randomization method. For allocation of the participants, an Excel generated list of random numbers will be used. The allocation sequence will be concealed in sealed, opaque envelopes. After the initial evaluation and obtaining the written consent of enrolled participants, the corresponding envelopes will be opened, and the treatment allocation will be revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

No. 67, West Jamali Alley., Wafamanesh Avenue, Heravi Square

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Postal code

1668753961

Approval date

2021-08-14, 1400/05/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.542

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

Score of Fatigue Severity

Timepoint

Fatigue Severity Scale (FSS) is evaluated before treatment, after 2 and 4 weeks.

Method of measurement

Fatigue Severity Scale Questionnaire

Secondary outcomes

1

Description

Score of Multiple sclerosis quality of life

Timepoint

Multiple sclerosis quality of life 54 (MSQOL-54) questionnaire is assessed before and after intervention.

Method of measurement

Multiple sclerosis quality of life 54 (MSQOL-54) questionnaire

Intervention groups

1

Description

Intervention group: The acupuncture group will receive acupuncture treatment through 10 sessions, 2-3 times per week (totally 4 weeks). All patients will also receive routine treatment with Interferon β-1a and Amantadine. According to textbooks and literature review, major selected acupoints for fatigue include Taixi (KI 3), Taichong (LR 3), Sanyinjiao (SP 6), Xuehai (SP 10), Zusanli (ST 36), Yanglingquan (GB 34), Guanyuan (CV 4),

Qihai (CV 6), and Hegu (LI 4). Sterile stainless steel acupuncture needles (0.25mm × 40mm, Zhongyan Taihe medical instrument, Beijing, China) were inserted perpendicularly at a depth of 10-15 mm into the acupoints and will be retained for 20 minutes.

Category

Treatment - Other

2

Description

Control group: Control group will receive routine treatment with Interferon β-1a and Amantadine. IFN-β-1a (Avonex), 30 µg, is administered by intramuscular injection once every week. Amantadine 100mg will be used orally once a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Faezeh Khodaie

Street address

Sina Hospital, Imam Khomeini Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amir Hooman Kazemi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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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