

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of adding electroacupuncture to common rehabilitation treatments on improving sensory and motor function and electrophysiological components in spinal cord injury patients

Protocol summary

Study aim

Investigating the effect of adding electroacupuncture to common rehabilitation treatments on improving sensory and motor function and electrophysiological components in spinal cord injury patients

Design

A clinical trial with a control group, double blind, block randomized, including 20 patients

Settings and conduct

Patients in Tehran Rofeydeh Hospital are divided into two groups of 10 people, in both groups, routine rehabilitation and electroacupuncture will be performed, but in the control group, after a few seconds, the device will be turned off and the needles will be removed. Before and immediately after 40 treatment sessions, the patients' sensory and motor function will be evaluated by the ASIA form and their H-reflex components will be recorded. In this study, the therapist, the evaluators, and the researcher are three different people, and the patients, evaluators, and the statistician are blinded.

Participants/Inclusion and exclusion criteria

20 patients with sub-acute spinal cord injury who are admitted to Rofeydeh Hospital for rehabilitation. Admission conditions: subacute traumatic spinal cord injury patients from the thoracic region and in groups B, C, and D (based on the American Spinal Injury Association injury scale). Normal or normal heart, liver and kidney functions as well as coagulation functions. Age 18-45 years. Exclusion criteria: uncontrolled blood pressure, deep vein thrombosis, severe pressure ulcers and cognitive dysfunction. diabetes Hypersensitivity to needles. pregnancy

Intervention groups

Intervention group (1): will receive routine rehabilitation treatment + electroacupuncture. Control group (2): They will receive routine rehabilitation treatment and the received electroacupuncture will be turned off after a few

seconds and the needles will be removed.

Main outcome variables

Sensory and motor performance and changes in electrophysiological components

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150602022539N14**

Registration date: **2023-02-23, 1401/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-23, 1401/12/04**

Update count: **0**

Registration date

2023-02-23, 1401/12/04

Registrant information

Name

Ziaeddin Safavi Farokhi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

zsafavi@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-03, 1401/01/14

Expected recruitment end date

2024-01-04, 1402/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of adding electroacupuncture to common rehabilitation treatments on improving sensory and motor function and electrophysiological components in spinal cord injury patients

Public title

The effect of electroacupuncture on sensory and motor function and electrophysiological components in spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Clinical diagnosis of Spinal Cord Injury with non-progressive causes characterized by spinal trauma. Neuroimaging tests, such as computed tomography, will be used to rule out more serious, progressive conditions such as nerve-destroying injuries, tumors, and demyelination. Patients with traumatic injury and relatively stable condition after spinal internal fixation surgery. Normal or normal heart, liver and kidney functions as well as coagulation functions. Being mentally and psychologically stable. Age range 18-45 years. Subacute traumatic spinal cord injury patients (maximum 18 months have passed since the injury) from the thoracic region and in groups B,C and D (based on the American Spinal Injury Association injury scale) will be studied.

Exclusion criteria:

Uncontrolled blood pressure, severe heart and lung disease, severe orthostatic hypotension, deep vein thrombosis, severe osteoporosis, severe pressure ulcers and cognitive dysfunction, diabetes, hypersensitivity to needles. Fear of needles. Pregnancy, osteomyelitis of vertebrae, tumor, ankylosing spondylitis. The presence of serious mental injuries such as suicidal thoughts. People suffering from complications such as hematoma or severe pain during the study. Lack of consent to continue the tests. People's inability to continue rehabilitation and intervention due to medical reasons. Participation of individuals in intensive rehabilitation programs that may bias the results will also be excluded.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block Randomization unit: individual Randomization tool: random sequence generation software (Excel) Random Layers: Does not occur How to make a random sequence: The method of allocation to two groups will be Block Permuted Randomization in blocks of 4. Concealment of random allocation: does not take place

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the therapist and the assessor (the one who evaluates the sensorimotor function using the ASIA form and the one who records the H-Reflex components) are different people, and the evaluator does not know what intervention the patient receives and also The statistician is also blind to the data.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Kilometer 5 Damghan road, Semnan

City

Semnan

Province

Semnan

Postal code

5319899951

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.SEMUMS.REC.1401.289

Health conditions studied**1****Description of health condition studied**

Spinal Cord Injury

ICD-10 code

S24.0

ICD-10 code description

Primary outcomes

1

Description

ASIA form sensory sub-item score - ASIA form motor sub-item score - H-reflex amplitude - H-reflex latency

Timepoint

Before treatment, immediately after 40 sessions of treatment

Method of measurement

ASIA form EMG recording device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive common rehabilitation treatment 6 days a week for 8 weeks and electroacupuncture 5 days a week for 8 weeks. Common rehabilitation includes that each patient will receive 6 days a week and three sessions of physiotherapy each day for forty-five minutes and one work session for thirty minutes, with at least one hour of rest between sessions. and the exercises will include strengthening exercises, stretching and passive exercises to prevent deformity and maintain joint range and walking exercises. The electroacupuncture protocol includes 40 sessions 5 days a week for 8 weeks with a frequency of 1-5 Hz and a pulse width of 100 microseconds with an intensity of 1 to 10 millivolts in the area of GV14, GV9, GV4, GV3, GV20, GV19 and Jiaji will be performed on the top and bottom of the injury site bilaterally for 30 minutes.

Category

Treatment - Devices

2

Description

Control group: The control group will receive common rehabilitation treatment 6 days a week for 8 weeks and electroacupuncture 5 days a week for 8 weeks, but after a few seconds the device will be turned off and the needles will be removed. Common rehabilitation includes that each patient will receive 6 days a week and three sessions of physiotherapy each day for forty-five minutes and one work session for thirty minutes, with at least one hour of rest between sessions. and the exercises will include strengthening exercises, stretching and passive exercises to prevent deformity and maintain joint range and walking exercises.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeydeh Rehabilitation Hospital

Full name of responsible person

Ziaeddin Safavi Farokhi

Street address

Rofeydeh Rehabilitation Hospital, Shahid Nemati Alley, South Salimi St., Anderzgo Blvd., Ghaitariya,

City

Tehran

Province

Tehran

Postal code

1935973476

Phone

+98 21 2220 5326

Email

ziasafavi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Street address

Mashahir Square, in front of Helal Ahmar, Semnan

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3332 2332

Email

ziasafavi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Position

Ph.D, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation faculty, Semnan University of Medical Sciences, Kilometer 5 of Damghan Road, Semnan

City

Semnan

Province

Semnan

Postal code

3013138111

Phone

+98 23 3365 4180

Email

ziasafavi@yahoo.com

Email

ziasafavi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

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Position

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3013138111

Phone

+98 23 3365 4180

Email

ziasafavi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Position

Ph.D, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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