Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

evaluation of rehabilitation and gait of SCI paraplegic patients using LEX mark 3 device

Protocol summary

Study aim

In this study, an attempt was made to stimulate lower limbs' muscles using surface electrodes with a uniquely programmed sequence to imitate passive physiological gait in patients with SCI and paraplegia.

Design

In this study, patients with SCI referred to Shohada-e-Tajrish Hospital and also patients registered in Tehran SCI Association are studied. Patients who comply with the research criteria will be included in the study. If the patient's muscles are fit, he/she first enters the muscle training phase. Upon completion of the mentioned phase, patients enter the standing phase. After being able to stand for 3-5 minutes, patients are allowed to walk with the device. Distance and duration of walking will be checked.

Settings and conduct

The study will be conducted at the Shohada-e-Tajrish Hospital Neurology Center and Khaje Nasiraldin Tusi University of Technology Development Center. First, the lower extremity muscles will be trained, then the patients will be assisted to perform the standing procedure. After acquiring the ability to stand for 3-5 minutes, patients will commence walking with help from the device.

Participants/Inclusion and exclusion criteria

inclusion criteria were lack of sense and movement in lower extremities. Absence of an ulcer at the junction of electrodes, malignancy, autosomal dysreflexia was ensured and all patients had complete function of their upper extremities. In case of contradicting any of the conditions mentioned above, the patients were excluded from the research

Intervention groups

In this study, a functional electrical stimulation device will be attached to the lower limbs of patients with spinal cord injury and the distance navigated by patients and duration of standing and ambulation will be investigated.

Main outcome variables

Patients will be able to stand and walk with the device's aid and hence prevent complications caused by inactivity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190225042840N1**
Registration date: **2019-10-18, 1398/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-18, 1398/07/26**
Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Sam alahyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 8669

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sam.alayari.md@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2021-03-02, 1399/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of rehabilitation and gait of SCI paraplegic patients using LEX mark 3 device

Public title

ambulation of SCI paraplegic patients with LEX mark 3

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

paraplegic patients with loss of sense in lower extremities. paraplegic patients with loss of voluntary movements. normal function of upper extremities.

Exclusion criteria:

autonomic dysreflexia presence of malignancy in lower extremities at electrode junctions presence of ulcer in lower extremities at electrode junctions any kind of deformity in lower extremities,trunk or upper extremities

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **8**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, all patients participating in the study received intervention including electrical stimulation of the lower limb and then variables including distance traveled, walking time, and standing time were evaluated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

loghman Hakim hospital, Makhsoos St., South Karegar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333631151

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.242

Health conditions studied

1

Description of health condition studied

paraplegic patients with thoracic spinal cord injury

ICD-10 code

S24.0XXS

ICD-10 code description

Concussion and edema of thoracic spinal cord, sequela

2

Description of health condition studied

lumbar spinal cord injury

ICD-10 code

S34.01XS

ICD-10 code description

Concussion and edema of lumbar spinal cord, sequela

Primary outcomes

1

Description

The first variable is the distance traveled by the patient using the device.Its definition includes the displacement performed by patients by lower extremities and with the aid of the device.

Timepoint

The time to measure this variable is at the end of each training session.

Method of measurement

The distance traveled by patients will be measured and recorded.

2

Description

The second variable in this study is the duration of walking and standing of each patient. Its definition includes amount of time spent by the patient walking and standing during a session.

Timepoint

The time to measure this variable is at the end of each training sessions.

Method of measurement

Minutes are route of measurement and reporting this variable.

3

Description
The third variable of the study is the number of sessions needed to train patients to use the device.
Timepoint
In this study, the number of sessions required for patients after completing their training is evaluated and calculated. The total number of sessions will be calculated when patients have the necessary ability to use the device to get up and walk.
Method of measurement
The number of patient training sessions will be recorded in the office and the number of sessions will be calculated based on the days recorded.

4

Description
The ambulation pace of patients is the result of the distance traveled by the duration of walking in each session.
Timepoint
At the end of each training session, the distance traveled by the patients is recorded and divided to the duration of travel.
Method of measurement
This variable is obtained by dividing the distance traveled by time. The unit of measurement is meters per second.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Paraplegic patients using a functional electrical stimulation device for rehabilitation
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e-Tajrish hospital
Full name of responsible person
Sam Alahyari
Street address
neurology section , Shohada-e-Tajrish hospital , Tajrish Sq., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Brain Mapping Center of Loghman Hakim Hospital
Full name of responsible person
Ali Amini Harandi
Street address
Brain mapping center , Loghman hakim hospital ,kamali St., south karegar Blvd., Tehran
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Fax
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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
Brain Mapping Center of Loghman Hakim Hospital
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sam Alahyari
Position
medical student
Latest degree
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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
This study will publish the data from the study in the article and ensure that no identifiable information is provided by the participants in the study.Also, if written consent is obtained from patients, photos or videos of patients standing and walking without their identity will be released.

When the data will become available and for how long
The research data will be completed by mid-1399 and will be available 5 months after the results are published in paper.

To whom data/document is available
The best target for data from this study are researchers and physicians. Other people associated with paraplegic individuals and patients such as associations and centers of spinal cord injury, disability support centers, rehabilitation centers, and even paraplegics are also able to use The information from this study will be. So information will be available.

Under which criteria data/document could be used
Applicants must state their request for information and its cause in a clear and concise manner. When using information at conferences and conferences, the principles of confidentiality must be followed and the source of information, including researchers, if the paper is prepared, The exact address of the article should also be mentioned. Also, if the data is used for other research, make sure to include it in the references section of the article.

From where data/document is obtainable
All applicants who receive information from this research can submit their request for research information to allahyarisam@yahoo.com or call 09370773786 or come to the Brain Mapping Center of Shahid Beheshti University of Medical Sciences and submit their written request.

What processes are involved for a request to access data/document
The applicant first submits his / her application via email or telephone. Then, his / her application will be reviewed

at the Brain Mapping Center of Shahid Beheshti University of Medical Sciences. If agreed, the requested information will be sent to the applicant within a maximum of ten business days.

Comments