Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of Effect of Robotic-Assisted Locomotor Training and Conventional Gait Training on Movement Pattern of Hip and Knee Joints in Sagittal Plane in Subjects with Chronic Incomplete Spinal Cord Iinjury

Protocol summary

Summary

The purpose of this study was the effect of robotic assissted gait therpay on kinematic gait parameters in Spinal cord injuries (16-55yrs). This was a Randomized Controlled Trial (RCT) study, that carried out on16 patients with chronic incompelete SCI. The volunteers were assigned in two control and experimental (robot therpay) groups after the initial assessment. kinematic gait parameters were evaluated by lokomoat system and FAM questionneare, WISCI II and ASIA were evaluated before and after interventions in both groups. The intervention sessions were designed in 3 days a week and will lasts 7 weeks. The period of treatment intervention was 30 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206071722N5**
Registration date: **2013-08-18, 1392/05/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7753 3939

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hadianrs@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study was supported by a grant from the postgraduate Studies and Research Program, Tehran University of Medical Sciences.

Expected recruitment start date

2010-10-12, 1389/07/20

Expected recruitment end date

2011-08-21, 1390/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Effect of Robotic-Assisted Locomotor Training and Conventional Gait Training on Movement Pattern of Hip and Knee Joints in Sagittal Plane in Subjects with Chronic Incomplete Spinal Cord Iinjury

Public title

Effect of Robotic-Assisted Locomotor Training and Conventional Gait Training on Movement Pattern of Hip and Knee Joints in Subjects with Chronic Incomplete Spinal Cord Iinjury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Patients with traumatic motor incomplete SCI with a neurologic lesion level of L1 or higher with at least one year after lesion; No Dependency on ventilator; Not currently enrolled in physical therapy or other training regimens; Male or Female between 16-55 yrs. old ;No clinically significant

sign, impairment or disease including: cardiovascular disease, respiratory disease, orthostatic hypotension, bladder and kidney disease, unhealed decubiti, pressure sore or bed sore, fracture and contracture. Decreased level of consciousness for more than 24 hours after trauma; No history of truamatic barin injury, contracture, hetropic ossification, osteoporosis, osteoarthritis; Score of Modefied Ashworth Scale in lower limb was 3 or less; Completing informed consent; Lokomat group were within the physical size of the Lokomat (ie, greater trochanter to lateral epicondyle 35 cm- 47 cm; pelvis width 50 cm, thigh circumference measured 14 cm above the knee axis 57 cm, and body weight 150 kg) Exclusion criteria: Any reaso that interfere with the continuation of treatment or withdrawal by patient ;No complete sessions of treatment in the current study

Age
From **16 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Ethical committee of Tehran University of Medical Sciences

Street address
6th floor, Central Building, Qods Street, Keshawarz Blv.

City
Tehran

Postal code
1449614535

Approval date
2012-11-07, 1391/08/17

Ethics committee reference number
92/130/1917/د

Health conditions studied

1

Description of health condition studied
Paraplegia and tetraplegia

ICD-10 code
G82.1

ICD-10 code description
congenital cerebral palsy

Primary outcomes

1

Description
Spasticity

Timepoint
before and after intervention

Method of measurement
Ashworth Scale

2

Description
American Spinal Injury Association(ASIA)

Timepoint
before and after intervention

Method of measurement
ASIA Form

3

Description
function

Timepoint
before and after intervention

Method of measurement
WISCI II, FAM Questionneare

4

Description
Cadence

Timepoint
before and after intervention

Method of measurement
observation

5

Description
Speed of walking

Timepoint
before and after intervention

Method of measurement
treadmill

6

Description
kinematic gait parameters

Timepoint

before and after intervention

Method of measurement

Lokomat system

Secondary outcomes

empty

Intervention groups

1

Description

Subjects in control group were treated by routine physical therapy. Conventional physical therapy consisted of Functional Electrical Stimulation (FES), weight bearing and overgound walking(Harness etal 2008).

Category

Rehabilitation

2

Description

Patients in case group were trained by Lokomat for 30 min.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal cord Injury Reseach Center (BASIR), Emam Khomeini Hospital

Full name of responsible person

Fatemeh Ghiasi

Street address

Emam Khomeini Hospital Complex, Keshavarz Blv

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of edical Sciences

Full name of responsible person

Vice chancellor for educational affairs, Tehran University of Medical Sciences

Street address

The Seventh Floor- Main Building Tehran University of Medical Sciences-Ghods Str-Keshavarz Boulevard

City

Tehran

Grant name

دانشگاه علوم پزشکی تهران

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of edical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Rehabilitation faculty, Tehran University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty