

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Injury

Protocol summary

hadianrs@sina.tums.ac.ir

Summary

The purpose of this study was the effect of robotic assisted gait therapy on kinematic gait parameters in Spinal cord injuries (16-55yrs). This was a Randomized Controlled Trial (RCT) study, that carried out on 16 patients with chronic incomplete SCI. The volunteers were assigned in two control and experimental (robot therapy) groups after the initial assessment. Kinematic gait parameters were evaluated by Lokomat system and FAM questionnaire, 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 last 7 weeks. The period of treatment intervention was 30 minutes.

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

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)

Phone

+98 21 7753 3939

Email address

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 Injury

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 Injury

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 traumatic brain injury, contracture, heterotopic ossification, osteoporosis, osteoarthritis; Score of Modified 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 reason that interferes 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

92/130/1917/5

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 Questionnaire

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 overground 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

Tehran

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

Fateme Ghiasi

Position

PhD student

Other areas of specialty/work

Street address

Rehabilitation faculty, Shahnazari street, Mirdamad
sq.

City

Tehran

Postal code

1148965141

Phone

+98 212227124

Fax

Email

f_ghiasi_p@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences,TUMS

Full name of responsible person

Dr. Mohammad Reza Hadian

Position

Professor, Faculty of Rehabilitation, TUMS

Other areas of specialty/work

Street address

Rehabilitation faculty, Shahnazari street, Mirdamad
Sq.

City

Tehran

Postal code

Phone

+98 212227124

Fax

Email

hadianrs@sina.tums.ac.ir; hadian_ras@yahoo.com

Web page address

+98 212227124

Fax**Email**

f_ghiasi_p@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences, Rehabilitation faculty,

Full name of responsible person

Fateme Ghiasi

Position

PhD student

Other areas of specialty/work**Street address**

Rehabilitation faculty, Shahnazari street, Mirdamad Sq.

City

Tehran

Postal code**Phone****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