

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effects of Robotic-Assisted Locomotor Training on quantity and quality of overground walking in subjects with chronic incomplete Spinal Cord Injury

Protocol summary

Summary

The purpose of this study is the effect of robotic assisted gait therapy on quality and quantity of gait function in Spinal cord injuries (16-55yrs). This is a Randomized Controlled Trial (RCT) study, and carried out on 24 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 Motion Captures Analysis and Lokomoat system and FAM, FIM, SCIM questionnaires, WISCI II and ASIA, Cadence, 2MWT, 10MWT, 6 MWT, Speed of walking was 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 is 30 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206071722N6**
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

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

2010-09-23, 1389/07/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Robotic-Assisted Locomotor Training on quantity and quality of overground walking in subjects with chronic incomplete Spinal Cord Injury

Public title

Effects of Robotic-Assisted Locomotor Training in subjects with chronic incomplete Spinal Cord Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: Patients with traumatic motor incomplete SCI with a neurologic lesion level of L1 or higher that at least one year passed the lesion; Not currently enrolled in physical therapy or other training regimens (Wirz et al 2005); Male or Female between ages 16 and 55; 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; No history of traumatic barin injury, contracture, hetropic ossification, osteoporosis, osteoarthritis ;Score Modefied Ashworth Scale in lower limb spasticity 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 included: Dependent on ventilator; Decreased level of consciousness for more than 24 hours after trauma; 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: **24**

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**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**

Spastic tetraplegia

ICD-10 code

G82.1

ICD-10 code description

congenital cerebral palsy

Primary outcomes**1****Description**

American Spinal Injury Association(ASIA) TEST

Timepoint

before and after intervention

Method of measurement

ASIA Form

2**Description**

Spasticity

Timepoint

before and after intervention

Method of measurement

Lokomat system and Ashworth Scale

3**Description**

muscle force

Timepoint

before and after intervention

Method of measurement

Lokomat system

4**Description**

function

Timepoint

before and after intervention

Method of measurement

FIM, FAM, SCIM, WISCI II

5**Description**

Speed of walking

Timepoint

before and after intervention

Method of measurement

treadmill

6**Description**

range of motion

Timepoint

before and after intervention

Method of measurement

7

Description

timing of movement

Timepoint

before and after intervention

Method of measurement

Lokomat system and Motion Captures Analysis

8

Description

gait evaluation

Timepoint

before and after intervention

Method of measurement

2MWT, 10MWT, 6MWT

Secondary outcomes

empty

Intervention groups

1

Description

After connecting patients in the exoskeleton of robotic system, physiological gait pattern was created and patients walking inside the Lokomat, 30 min.

Category

Rehabilitation

2

Description

Subjects in conventional group treated to routine physical therapy. Conventional physical therapy consisted of Functional Electrical Stimulation (FES), weight bearing and overground walking (Harness et al 2008).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal cord Injury Research Center (BASIR)

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 Medical Sciences (TUMS)

Full name of responsible person

Dr. Mohammad Jalili

Street address

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

City

Tehran

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 (TUMS)

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, Pich e Shemiran, Enghlab Street

City

Tehran

Postal code

1148965141

Phone

+98 21 7753 6134

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, pich e shemiran, enghlab street

City

Tehran

Postal code

Phone

+98 21 7753 6134

Fax

Email

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

Web page address

Person responsible for updating data

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,Pich e Shemiran,Enghlab Street

City

Tehran

Postal code

1148965141

Phone

+98 21 7753 6134

Fax

Email

f_ghiasi_p@yahoo.com

Web page address

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