Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Summary

The purpose of this study is the effect of robotic assissted gait therpay on quality and quantity of gait function in Spinal cord injuries (16-55yrs). This is a Randomized Controlled Trial (RCT) study, and carried out on24 patients with chronic incompelete SCI. The volunteers were assigned in two control and experimental (robot therpay) groups after the initial assessment. kinematic gait parameters was evaluated by Motion Captures Analysis and lokomoat system and FAM , FIM , SCIM questionneares, WISCI II and ASIA, Cadence, 2MWT, 10MWT, 6 MWT , Speed of walking was evaluated before and after interventions in both groups. The intervention sessions was designed in 3 days a week and will lasts 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 Iinjury

Public title

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

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 etal 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 truamatic 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/د

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

Lokomat system and MOtion Captures Analysis

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 exoskeletone 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 overgound walking(Harness etal 2008).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Brain and Spinal cord Injury Reseach 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