

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of 24 weeks advanced weight-bearing exercises with/without quadriceps and soleus functional electrical stimulation on femoral and tibial bone density indexes and functional activities in paraplegic spinal cord injury

Protocol summary

Summary

(1)Objectives: Bone unloading due to muscle paralysis and immobility is one of the most important factors in the decline of bone mass in patients with spinal cord injury. Bones of the lower extremities in patients not receiving compressive forces caused by the weight bearing and not tensile forces caused by the contraction of muscle; So this mechanical loading by weight bearing exercises and functional electrical stimulation may be limited or improve reduce of bone density. (2)Design: Randomize control trial (3)Setting and conduct: 30 volunteers divided into 3 groups (exercise, exercise with electrical stimulation and control). Exercise group and exercise with electrical stimulation group undergo interventions for 24 weeks. Quantitative compute tomography will be taken from the distal femur and proximal tibia in both legs for all patients before and after the 24 weeks. (4)Participants including major eligibility criteria: Patients with chronic paraplegic spinal cord injury (between T2 up T12, grade A or B) (5)Intervention: Advanced weight-bearing exercises including trunk twisting and raising, quadruped, tall-kneeling with Weight shifting to different directions, alternative isometric and rhythmic stabilization contractions, and forward reaching along with functional electrical stimulation of quadriceps and soleus muscles. (6)main outcome measures (variables): Total bone mineral density, trabecular bone mineral density, cortical bone mineral density, cortical thickness, cortical cross section area and total cross section area will be measured. Also in order to assess the level of independence in daily activities and the patient's general health survey, the Persian version of the Barthel index and the SF-36 questionnaire is used. Functional and stability performance be evaluated with the number of practice of trunk twisting and raising exercise, and time

exposure of quadruped, forward reaching and tall-kneeling positions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304084952N3**

Registration date: **2016-11-22, 1395/09/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

Name

Giti Torkaman

Name of organization / entity

Tarbiat Modares University

Country

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+98 21 8288 4509

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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 24 weeks advanced weight-bearing exercises with/without quadriceps and soleus functional electrical stimulation on femoral and tibial bone density indexes and functional activities in paraplegic spinal cord injury

Public title

Treatment of osteoporosis in patients with spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion major criteria: Traumatic paraplegic spinal cord injury (T6 up T12 ,grade A or B); Since the lesion is at least 1 year; Age between 20 and 40 years; Ability to respond to electrical stimulation of the quadriceps and soleus muscles; Normal rang of motion in the hip, knee and ankle joints; medically stable; No previous fracture in areas that are scanned; No history of metabolic diseases and other disorders affecting calcium metabolism and density of bone, early menopause, cancer, arthritis, diabetes; No use the certain drugs affecting bone metabolism including steroids, estrogens, bisphosphonates and calcitonin, fluorides, thyroid hormones, lithium, anticonvulsants and anti-androgen; No routine and regular physiotherapy including weight bearing exercise program and electrotherapy during past 6 months. Exclusion major criteria: Lack of patient's cooperation; Creation of some problems such as fractures, infections.

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Tarbiat modares university

Street address

Jalal Al Ahmad Street

City

Tehran

Postal code

14115-111

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.TMU.REC.1395.364

Health conditions studied**1****Description of health condition studied**

Thoracic spinal cord injury

ICD-10 code

S24.1

ICD-10 code description

Other and unspecified injuries of thoracic spinal cord

2**Description of health condition studied**

Lumbar spinal cord injury

ICD-10 code

S34.1

ICD-10 code description

Other injury of lumbar spinal cord

3**Description of health condition studied**

Osteoporosis

ICD-10 code

M81

ICD-10 code description

Osteoporosis without pathological fracture

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

Total bone mineral density

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

2**Description**

Total cross section area

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

3**Description**

Trabecular bone mineral density

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

4**Description**

Cortical cross section area

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

5**Description**

Cortical bone mineral density

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

6**Description**

Cortical thickness

Timepoint

Before and after 24 weeks intervention

Method of measurement

quantitative compute tomography

7**Description**

Number of practice of trunk twisting and raising exercise

Timepoint

Before and after 24 weeks intervention

Method of measurement

Count

8**Description**

Time exposure of quadruped position

Timepoint

Before and after 24 weeks intervention

Method of measurement

Digital timer

9**Description**

Time exposure of tall-kneeling position

Timepoint

Before and after 24 weeks intervention

Method of measurement

Digital timer

10**Description**

Time exposure of forward reaching position

Timepoint

Before and after 24 weeks intervention

Method of measurement

Digital timer

Secondary outcomes**1****Description**

Patient's general health survey

Timepoint

Before and after 24 weeks intervention

Method of measurement

Persian version of the SF-36 questionnaire

2**Description**

Level of independence in daily activities

Timepoint

Before and after 24 weeks intervention

Method of measurement

Persian version of the Barthel index

Intervention groups**1****Description**

First group: Patients who are undergo advanced weight bearing exercises (quadruped, trunk twisting and raising, tall-kneeling).

Category

Treatment - Other

2**Description**

Third group: Control group, No intervention

Category

Other

3**Description**

Second group: Patients who will do trunk twisting and raising exercise alone and do quadruped and tall-kneeling with quadriceps and soleus functional electrical stimulation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical therapy of Mostafa Rahimi

Full name of responsible person

Mostafa Rahimi

Street address

No.34, south Taheri alley, west 196 St, Tehranpars

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tarbiat modares university

Full name of responsible person

Dr Yaghoob Fatollahi

Street address

Jalal Al Ahmad St

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Tarbiat modares university

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**

Tarbiat Modares university

Full name of responsible person

Mostafa Rahimi

Position

Student

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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