# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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-knelling 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**
Iran (Islamic Republic of)
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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-knelling 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
**City**
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 Fatolahi
**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*