

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of combination of whole body vibration training and strength exercise training versus strength exercise training on knee osteoarthritis complications in patient with knee osteoarthritis

#### Protocol summary

##### Summary

**Objectives:** Osteoarthritis (OA) has been considered as one of the widespread diseases, which mostly occurs in knee joint. American College of Rheumatology (ACR) has recommended muscle strengthening protocols for management of knee OA symptoms. Recently it has been advised to use Whole Body Vibration (WBV) for the knee OA treatment. This study has been designed to investigate the effect of combination of WBV training and strengthening exercise on complications of knee OA.

**Setting and conduct:** Patients with bilateral or unilateral knee OA will be randomly allocated in one of the control (quadriceps strengthening exercise) and experimental (WBV plus quadriceps strengthening exercise) groups. Participants including major eligibility criteria (patients with mild to moderate knee joint symptoms in tibiofemoral joint according to the ACR scales) will be participated in the study. They will be excluded from the study if there is musculoskeletal, neuromuscular, cardiovascular, diabetic and respiratory diseases, history of lower limb fracture for the last year, history of severe trauma to the lower limbs during last three months.

**Intervention:** Experimental group perform quadriceps strengthening exercise, plus WBV training 3 times in a week for 8 weeks, while control group performs quadriceps strengthening exercise, 3 times in a week for 8 weeks. Main Outcome measure variables: The torque of quadriceps and hamstring muscles, pain, functional activities and quality of life will be evaluated before and immediately after intervention and also after 4 weeks follow-up.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201206065152N2**

Registration date: **2012-07-16, 1391/04/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-07-16, 1391/04/26

##### Registrant information

###### Name

HamidReza Bokaiyan

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 1333 2329

###### Email address

boka@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Semnan University of Medical Sciences

##### Expected recruitment start date

2012-09-05, 1391/06/15

##### Expected recruitment end date

2013-09-06, 1392/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of combination of whole body vibration training and strength exercise training versus

strength exercise training on knee osteoarthritis complications in patient with knee osteoarthritis

### Public title

Investigation the effect of combination of whole body vibration training and strength exercise training on the knee osteoarthritis complication

### Purpose

Treatment

### Inclusion/Exclusion criteria

Included criteria: suffering from chronic osteoarthritis of knee [bilateral and unilateral], with mild to moderate symptoms in tibiofemoral joint; age 35 to 76; to have pain and disability of knee over one month; to have resented lateral and AP radiography image of knee.

Excluded criteria: suffering to disease such as diabetes, musculoskeletal disorder, neuromuscular disorder, cardiovascular disorder, respiratory disease and else; consumption of injection or other aggressive therapies (like surgery) of lower limbs during 3 last months; consumption of drug; to have artificial knee or artificial hip; experience of trauma to knee joint; experience of regular professional physical activity; sever physical disability; disability in walk with or without assistive device.

### Age

From **35 years** old to **76 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **32**

### 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

b

##### Street address

Semnan university of medical sciences

##### City

semnan

### Postal code

### Approval date

2012-10-17, 1391/07/26

### Ethics committee reference number

91/216810

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis of knee

#### ICD-10 code

M17

#### ICD-10 code description

(Gonarthrosis (arthrosis of knee

## Primary outcomes

### 1

#### Description

muscle strength,total work, muscle power

#### Timepoint

before intervention, after intervention

#### Method of measurement

used from Isokinetic Dynamometer Biodex System

### 2

#### Description

pain

#### Timepoint

before intervention, after intervention

#### Method of measurement

VAS scale

### 3

#### Description

quality of life

#### Timepoint

before intervention, after intervention

#### Method of measurement

WOMAC scale

### 4

#### Description

functional activity

#### Timepoint

before intervention, after intervention, 4 weeks after end of intervention

#### Method of measurement

2 minute walk test, The timed up & go test, Timed 50 foot walk test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

group 1: 1)convention electrothrapy 2) 3 set flexion and extension of knee joint for strengthening exercise. in the first set patient train with 60 to 65 percent of 10 RM. in the secondary set patient train with 70 to 75 percent of 10 RM. in the end set patient train with 80 to 85 percent of 10 RM. there is 2 minutes rest time between training sets.

#### Category

Treatment - Other

### 2

#### Description

group 2: 1)convention electrothrapy 2) 3 set flexion and extension of knee joint for strengthening exercise. in the first set patient train with 60 to 65 percent of 10 RM. in the secondary set patient train with 70 to 75 percent of 10 RM. in the end set patient train with 80 to 85 percent of 10 RM. there is 2 minutes rest time between training sets.3) patient stand up on the platform of WBV with her/his legs beside.6 set with 30 second platform oscillate to sagital axes. there is 30 seconds rest time between training sets.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neuromuscular Rehabilitation Research Center

##### Full name of responsible person

Amir Hushang Bakhtiary

##### Street address

Neuromuscular Rehabilitation Research Centre,  
Ghods Avenue

##### City

Semnan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research, Semnan University of  
Medical Sciences

##### Full name of responsible person

Dr Raheb Ghorbany

##### Street address

Semnan University of Medical Sciences, Basij Blv.

##### City

Semnan

#### 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, Semnan University of  
Medical 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

Semnan University of Medical Sciences

##### Full name of responsible person

Hamid Reza Bokaiian

##### Position

student of post gaduate

##### Other areas of specialty/work

##### Street address

Andishe bedchamber, 17 Shahrivar boulevard

##### City

Semnan

##### Postal code

##### Phone

+98 23 1332 8230

##### Fax

##### Email

hamid\_boka67@yahoo.COM

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Neuromuscular Rehabilitation Research Centre,  
Semnan University of Medical Sciences

##### Full name of responsible person

Amir Hushang Bakhtiary

##### Position

Full Professor/PhD

##### Other areas of specialty/work

##### Street address

Neuromuscular Rehabilitation Research Centre, Gods  
Ave.

##### City

Semnan

##### Postal code

##### Phone

+98 23 1335 4170

##### Fax

##### Email

amir822@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Neuromuscular Rehabilitation Research Centre,  
Semnan University of Medical Sciences

**Full name of responsible person**

Amir H Bakhtiary

**Position**

Full Professor/PhD

**Other areas of specialty/work**

**Street address**

Ghods Avenue

**City**

Semnan

**Postal code**

**Phone**

00

**Fax**

**Email**

amir822@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*