

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of Spinomed Orthosis on Effective parameters in Elderly's Balance performance with Hyperkyphosis

#### Protocol summary

##### Summary

The first aim of this study is to investigate the effect of orthosis on proprioception, force sense, and muscle endurance. A second aims to verify whether decrease in thoracic curve will be associated with improvement in forward head posture, and in finally investigate the relationship between changes in thoracic proprioception, force sense, extensor muscle endurance, thoracic kyphosis and forward head posture with balance performance. This study is a parallel group randomized controlled trial. The sample size will be 44 subject. Older adults (age $\geq$ 60 years) with thoracic kyphosis angle  $\geq$  50 and capability of walking without assistive devices will be eligible. Subjects with history of cervical, spinal or lower limb fracture and/or trauma, severe spinal pathologies and deformities, cervical and spinal surgery, disease of the central nervous system, neuromuscular disorder, and severe osteoporosis, will be excluded. Furthermore, using of drugs known to affect the central nervous system or equilibrium, and muscle strength will be led to exclusion. Subjects in the experimental group will receive Spinomed. Subject 13 weeks will be instructed to wear Spinomed for 2-4 h daily with keep daily physical activity in the orthosis group and keep daily physical activity in the control group. In this study we will measured thoracic kyphosis with inclinometer, proprioception and force sense with re-position error test, muscle endurance with Ito test, forward head posture with craniovertebral angle and balance with berg balance scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080335480N1**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-02, 1396/07/10

##### Registrant information

###### Name

Mostafa Hosseinabadi

###### Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2222 8051

###### Email address

hosseinabadi.m@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2017-09-25, 1396/07/03

##### Expected recruitment end date

2018-01-04, 1396/10/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Spinomed Orthosis on Effective parameters in Elderly's Balance performance with Hyperkyphosis

##### Public title

spinal orthotic management of the elderly people with hyperkyphosis

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion: age  $\geq 60$  years kyphosis angle  $\geq 50$  capability of walking without assistive devices Exclusion: with history of cervical, spinal or lower limb fracture and/or trauma, severe spinal pathologies and deformities, cervical and spinal surgery, inflammatory diseases such as ankylosing spondylitis, rheumatoid arthritis, disease of the central nervous system, neuromuscular disorder, diabetic neuropathy, vestibular disease, dizziness, uncorrectable visual or vestibular impairments, Severe osteoporosis, foot deformities using of drugs known to affect the central nervous system or equilibrium (i.e., sedatives or anxiolytics), and of drugs known to affect muscle strength (i.e., corticosteroids), back or neck pain at the time of examination reported to be higher than 3 on the Visual Analogue Scale (VAS), and inability to put on Spinomed

### **Age**

From **60 years** old to **80 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **44**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Iran University of Medical Sciences

##### **Street address**

Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2017-05-22, 1396/03/01

#### **Ethics committee reference number**

IR.IUMS.REC 1396.9411502002

## **Health conditions studied**

### 1

#### **Description of health condition studied**

kyphosis

#### **ICD-10 code**

M40.1

#### **ICD-10 code description**

Other secondary kyphosis

## **Primary outcomes**

### 1

#### **Description**

Muscle Endurance

#### **Timepoint**

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

#### **Method of measurement**

Ito Test and chronometer

### 2

#### **Description**

Forward Head Posture

#### **Timepoint**

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

#### **Method of measurement**

Photographic and Craniovertebral Angle

### 3

#### **Description**

proprioception

#### **Timepoint**

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

#### **Method of measurement**

Re-position Error Test and Inclinometer

### 4

#### **Description**

Force Sense

#### **Timepoint**

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

#### **Method of measurement**

Re-position Error Test and Dynamometer

### 5

#### **Description**

Balance

#### **Timepoint**

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

#### **Method of measurement**

Berg Balance Scale and Timed up and Go Test

## 6

### Description

Kyphosis

### Timepoint

Before Intervention,5 weeks After Intervention,9 weeks  
After Intervention,13 weeks After intervention

### Method of measurement

Inclinometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Spinomed Orthosis, 2 weeks 30 Minutes per Day, 3  
Weeks 2 Hour per Day, and 8 Weeks 2-4 Hour per Day

#### Category

Treatment - Other

### 2

#### Description

No treatment

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nursing Homes

##### Full name of responsible person

##### Street address

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Day Care Centers

##### Full name of responsible person

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Ali Javad Moosavi

#### Street address

Hemmat Highway, Iran University of Medical Sciences

#### City

Tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Iran 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

School of Rehabilitation Sciences, Iran University of  
Medical Sciences

#### Full name of responsible person

Mostafa Hosseinabadi

#### Position

Postgraduate Student in Prosthetics & Orthotics

#### Other areas of specialty/work

#### Street address

School of Rehabilitation Sciences, Nezam Alley,  
Shahnazari St. Madar Sq. Mirdamad Blv.

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Mojtaba Kamyab

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Ph.D in Prosthetics & Orthotics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
School of Rehabilitation, Iran University of Medical Sciences  
**Full name of responsible person**  
Mostafa Hosseinabadi  
**Position**  
Postgraduate Student in Prosthetics & Orthotics  
**Other areas of specialty/work**  
**Street address**  
**City**

## 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*