

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

A comparison on the effects of spinomed orthosis and posture - training support on risk of falling in elderly patients with spinal hyperkyphosis

Protocol summary

Summary

The purpose of this study is a comparison on the effects of spinomed orthosis and posture-training support on risk of falling in elderly patients with spinal hyperkyphosis. The study includes local women and men who are older than 60 yr. The other inclusion criteria are the presence of thoracic kyphosis, measured on standing lateral radiography of the spine, showed a Cobb angle ≥ 50 . Subjects are not included in the study if they have a history of any progressive neurogenic or myopathic disorder that is known to impair motor function or if they are receiving drugs known or presumed affect the central nervous system or equilibrium. The duration of wearing of orthosis in each groups is considered for one and half in order to adapt with orthosis. The sample size is approximately 28 persons according to the formula. Then they are randomly allocated into one of the three groups (spinomed, posture training support or control). Patients were randomly subjected to computerized dynamic posturography, which contained sensory organization tests (SOT) and limits of stability (LOS). The tests for each person was conducted in two conditions: while wearing and not wearing the orthosis, and the order of testing within a patient was randomized. The indices of LOS test are reaction time and directional control. The index of SOT includes the composite balance score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101065520N3**

Registration date: **2011-01-28, 1389/11/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-28, 1389/11/08

Registrant information

Name

Mojtaba Kamyab

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2010-01-21, 1388/11/01

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison on the effects of spinomed orthosis and posture - training support on risk of falling in elderly patients with spinal hyperkyphosis

Public title

A comparison on the effects of two type spinal orthosis on balance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- they older than 60 yr. 2- cobb angle \geq 50. Exclusion criteria: 1- they are receiving drugs known or presumed to affect the central nervous system or equilibriums. 2- they have a history of any progressive neurogenic or myopathic disorder 3- having confirmed scoliosis with Adamz test 4- joint replacement in the lower extremities 5- uncorrectable visual and vestibular deficits 6- having the history of any fracture or operation in spine or lower extremity 7- attending precedent in balance spinal exercises 8- the existence of low back or cervical pain on the test session which is rated by the patient more than 3 degree on visual analysis scale

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: **28**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Faculty of rehabilitation, Tehran university of medical sciences

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Faculty of rehabilitation, shahnazari street, Mader squ, Mirdamad blvd

City

Tehran

Postal code**Approval date**

2010-01-13, 1388/10/23

Ethics committee reference number

221

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

hyperkyphosis

ICD-10 code

R29.3

ICD-10 code description

Abnormal posture

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

Balance score

Timepoint

before intervention and one and a half hour after intervention

Method of measurement

a score from 0 to 100 by Equi Test System

2**Description**

Directional control

Timepoint

before intervention and one and a half hour after intervention

Method of measurement

as a percentage by Balance Master System

3**Description**

Reaction time

Timepoint

before intervention and one and a half after intervention

Method of measurement

as a percentage by Balance Master System

Secondary outcomes

empty

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

Spinomed orthosis (intervention group)

Category

Other

2**Description**

Posture Training Support (intervention group)

Category

Other

3**Description**

Placebo orthosis (control group)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Hamid Behtash private clinic

Full name of responsible person

Dr. Hamid Behtash

Street address

9 unite, 4th floor, 9 number, 8th Avenue. Miremad street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. M.Moradi Lakeh

Street address

Vice-Chancellor for Research, Tehran University of Medical Sciences

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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, Tehran 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

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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