Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the effect of hyperkyphosis orthosis and postural kinesiotaping on spino-pelvic sagittal alignment and postural control strategy of the elderly with hyperkyphosis

Protocol summary

Study aim
Evaluation of the effect of orthosis and taping not only in correction of thoracic spine alignment but also pelvic and cervical alignment and also its effect on postural control strategies

Design
Randomized clinical trial, with parallel groups and single-blind on 48 patients. Randomizer site will be used for randomization.

Settings and conduct
The study will be conducted in the Faculty of Rehabilitation of Iran University of Medical Sciences. Spinal and pelvis sagittal alignment will be examined by radiography and postural control by a force plate, and the data analyzer will be blind to type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age more than 60 years, kyphosis angle more than 50 degree, capability of walking without assistive devices Exclusion criteria: history of fracture or trauma to the spine and lower extremities, history of spinal surgery, history of inflammatory diseases such as ankylosing spondylosis, rheumatoid arthritis, history of central nervous system diseases, neuromuscular disorders and diabetes neuropathy, bone density with a T-score less than -1, history of vestibular disease and dizziness, history of cardiovascular diseases, history of diseases of the lymphatic and kidney system, visual and auditory disorders that can not be corrected, history of falls more than twice in the last six months, history of knee osteoarthritis, cognitive impairment with AMTS≤6 score, use of drugs affecting the central nervous system or balance, inability to wear orthoses, sensitivity to taping

Intervention groups
In group one, orthosis will be worn for 13 weeks for two hours a day, in group two for 13 weeks, postural tape will be received. There will be 2 taping programs per week for up to 13 weeks.

Main outcome variables
Spinal and pelvis sagittal alignment; Nonlinear and linear analysis of postural control, balance performance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170803035480N2**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**
Update count: **0**

Registration date
2022-06-21, 1401/03/31

Registrant information

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Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of hyperkyphosis orthosis and postural kinesiotaping on spino-pelvic sagittal alignment and postural control strategy of the elderly with hyperkyphosis

Public title
Comparison of the effect of orthosis and kinesiotaping on posture and balance of the elderly with hyperkyphosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age≥60 years Kyphosis angle ≥ 50 Capability of walking without assistive devices

Exclusion criteria:
History of cervical, spinal or lower limb fracture and/or trauma, severe spinal pathologies and deformities, cervical and spinal surgery History of inflammatory diseases such as ankylosing spondylitis, and rheumatoid arthritis History of disease of the central nervous system, neuromuscular disorder, and diabetic neuropathy Bone mineral density with T-Score less than -1 History of vestibular disease, and dizziness Foot deformities History of cardiovascular disease History of diseases of the lymphatic and kidneys system Uncorrectable visual or vestibular impairments History of joint replacement in the lower limb History of falls more than twice in the last six months History of grade 2 and 3 osteoarthritis of the knee based on the Kellgren-Lawrence scale in one or both legs Cognitive impairment with AMTS≤6 score Taking drugs known to affect the central nervous system or equilibrium inability to put on orthosis taping Sensitivity

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to divide participations into two intervention groups, will be prepared lists of random numbers and patients will be assigned to two groups based on random blocking that will be made by the software. In order to conceal the allocation, the codes determining the type of intervention will be kept in sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyzer is kept blind to the type of intervention

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

Province
Tehran

Postal code
1449614535

Approval date
2022-05-31, 1401/03/10

Ethics committee reference number
IR.IUMS.REC.1401.180

Health conditions studied

1

Description of health condition studied
Thoracic kyphosis

ICD-10 code
M40.1

ICD-10 code description
Other secondary kyphosis

Primary outcomes

1

Description
Thoracic Kyphosis

Timepoint
Before intervention, 3 months after intervention

Method of measurement
EOS radiography

Secondary outcomes

1

Description
Lumbar lordosis
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

2

Description
Pelvic Incidence
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

3

Description
Pelvic Tilt
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

4

Description
Sacral Slope
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

5

Description
Sagittal Vertical Axis
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

6

Description
Cervical Sagittal Vertical Axis
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

7

Description
T1 Slope
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

8

Description
Cervical Lordosis
Timepoint
Before intervention and 3 months after intervention
Method of measurement
EOS radiography

9

Description
Open loop control
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

10

Description
close loop control
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

11

Description
Critical displacement
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

12

Description
Critical time
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

13

Description
Anteroposterior mean velocity
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

14

Description
Radial mean velocity
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

15

Description
Sway area per unit time
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Force plate

16

Description
Balance performance
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Mini balance evaluation systems test

Intervention groups

1

Description
Intervention group: orthosis
Category
Rehabilitation

2

Description
Intervention group: kinesiotaping
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation school of Iran university of medical sciences
Full name of responsible person
Behnam Hajiaghaei
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School of Rehabilitation Sciences, Madadkaran Alley, Shah'nazari St. Madar Sq. Mirdamad Blv.
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Sponsors / Funding sources

1

Sponsor
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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
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after encoding and being unrecognizable
When the data will become available and for how long
6 months after publish
To whom data/document is available
Only for researchers in academic and scientific institutions
Under which criteria data/document could be used
For use in systematic review and meta-analysis articles
From where data/document is obtainable
Corresponds author
What processes are involved for a request to access data/document
After email to the corresponds author and with the approval of co-author
Comments