Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of 16 sessions core stabilization exercises on spine kinematics during walking both with and without load in patients with non-specific chronic low back pain and comparison with healthy control group

Protocol summary

Study aim
The aim of this study is to evaluate the effect of spinal stabilization exercises on the spine kinematics during walking.

Design
A concealed, controlled clinical trial with a parallel group design of 30 patients healthy

Settings and conduct
Patients with a history of at least 3 months Non-specific chronic Low Back Pain (NCLBP) in the range of 18-45 years will enrolled after filling out a consent form. Each patient will complete the perceived pain questionnaire and the Oswestry Disability Questionnaire. Then in the first session, the spine kinematics will be evaluated in the motion analysis laboratory. Markers are placed on the trunk (acromion process and T12), lumbar (T12, L3 and S2), pelvis (bilateral ASIS and PSIS) and foot (bilateral posterior heel center and fifth MTP) and the patient is asked to walk with self-selected daily speed in a direction of 10 meters at a rate of 3 times without load and 3 times with a load approximately 10% of their body weight. Then, each patient participate in the 16 sessions of patient-specific spinal stabilization exercise training that will be given three times a week for 6 weeks. In the final session, pain, disability and spinal column kinematic will be assessed.

Participants/Inclusion and exclusion criteria
Inclusion: Low back pain from lower thorasic rib to the upper gluteal fold lasted more than 12 weeks. The range of pain would between 3-6 according to the VAS
Exclusion: acute low back pain, any illness and disorders in other limbs, gait disturbance, Any medical condition who have contraindications to exercise therapy.

Intervention groups
16 sessions of patient-specific spinal stabilization exercise training in patients group, no intervention will be made in the control group.

Main outcome variables
pain, disability and kinematic parameters of the spine

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2016080829264N1**
Registration date: **2016-08-28, 1395/06/07**
Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **1**

Registration date
2016-08-28, 1395/06/07

Registrant information

Name
Rasool Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3344 1022

Email address
rasool.bagheri@ymail.com

Recruitment status
Recruitment complete

Funding source
IRAN University of Medical Sciences

Expected recruitment start date
2016-09-22, 1395/07/01

Expected recruitment end date
2017-04-19, 1396/01/30

Actual recruitment start date
2016-10-18, 1395/07/27

Actual recruitment end date
2017-04-08, 1396/01/19
Trial completion date
2017-06-10, 1396/03/20

Scientific title
The effect of 16 sessions core stabilization exercises on spine kinematics during walking both with and without load in patients with non-specific chronic low back pain and comparison with healthy control group

Public title
The effects of spinal specific exercise therapy for treatment of chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Low back pain from lower thorasic rib to the upper gluteal fold low back pain which lasted more than 12 weeks The range of pain would between 3-6 according to the VAS
Exclusion criteria:
Any medical condition who have contraindications to exercise therapy. Acute low back pain or back pain that occurred in less than 12 weeks. BMI above 25 kg/m2. Sciatic nerve root involvement. Pain radiating to the leg below the knee. Feeling paresthesia in the legs. Motor deficits in the lower limb muscles (MMT, grade 3.5 and less on the basis of Kendall approach). Acute spinal disc herniation (MRI reports or medical reports). History of surgery and lumbar spine fractures or other spinal structures (self-reported). Malignancy(self-reported). Pregnancy(self-reported). Radicular symptoms during daily activities, especially walking (self-reported). During the intervention, the patient will be banned from any sports activities.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
N/A
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
Ethics committee of IRAN University of Medical Science
Street address
"Next to the Milad Hospital" "Hemmat Highway"
City
Tehran
Province
Tehran
Postal code
3513138111
Approval date
2016-07-31, 1395/05/10
Ethics committee reference number
IR.IUMS.REC 1395.9211342205

Health conditions studied

1

Description of health condition studied
chrionic low back pain
ICD-10 code
M54.5
ICD-10 code description
Loin pain, Low back strain

Primary outcomes

1

Description
spinal kinematic
Timepoint
before and after treatment
Method of measurement
motion analysis system of qualysis

2

Description
disability
Timepoint
before and after treatment
Method of measurement
ODI disability quasionnare

3

Description
pain
Timepoint
before and after treatment

Method of measurement
100 mm VAS scale

Secondary outcomes

1

Description
pain due to the core stabilization exercise
Timepoint
during assessment and treatment
Method of measurement
self reported

Intervention groups

1

Description
specific spinal stabilization exercise that lasted in 16 sessions and 6 weeks and 3 times in each week. each session lasted for 45 minutes.
Category
Rehabilitation

2

Description
In control healthy subjects, There will be no intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation
Full name of responsible person
Rasool Bagheri
Street address
"Madadkaran Alley" "Shahnazari Street" "Madar Squar"
City
Tehran
Province
Tehran
Postal code
3513135111
Phone
+98 21 2222 0946
Email
rasool.bagheri@ymail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ismail Ebrahimi Takamjani
Street address
"Madadkaran Alley" "Shahnazari Street" "Madar Squar"
City
Tehran
Province
Tehran
Postal code
3513135111
Phone
+98 21 2222 0946
Email
driebrahimi@yahoo.com
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

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Ismail Ebrahimi Takamjani
Position
Ph.D of Physiotherapy
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
"Madadkaran Alley" "Shahnazari Street" "Madar Squar"
City
Tehran
Province
Tehran
Postal code
3513135111
Phone
+98 21 2222 8051
Fax
Email
rasool.bagheri@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Ismail Ebrahimi Takamjani

Position
Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
"Madadkaran Alley" "Shahnazari Street" "Madar Squar"

City
Tehran

Province
Tehran

Postal code
3513135111

Phone
+98 21 2222 8051

Fax

Email
rasool.bagheri@ymail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Rasool Bagheri

Position
Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
"Madadkaran Alley" "Shahnazari Street" "Madar Squar"

City
Tehran

Province
Tehran

Postal code
3513135111

Phone
+98 21 2222 8051

Fax

Email
rasool.bagheri@ymail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available