

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of walking on postural reactions, pain and disability in patients with non-specific chronic low back pain

Protocol summary

Study aim

Investigating the effect of walking on postural reactions, pain and disability in non-specific chronic low back pain patients

Design

The study will be a clinical trial type with two control groups with routine physiotherapy treatment and an intervention group with walking exercises on a treadmill on 30 patients.

Settings and conduct

This study will be conducted in Zahedan, Razmjomoghadam Physiotherapy Clinic of Medical Sciences University on volunteer patients with non-specific chronic back pain. Patients will be randomly assigned to one of the groups of routine treatment and walking therapy.

Participants/Inclusion and exclusion criteria

Entry requirements: 1) Women and men aged between 18-45 years 2) Chronic back pain in the area between the twelfth rib and the rump without reference to the lower limbs that lasts for more than three months and has no specific cause. 3) Ability of patients to walk for 20 minutes daily Conditions of non-entry: 1) Having a history of neurological disorder 2) Rheumatic and inflammatory diseases 3) Cancer 4) Spinal cord lesions 5) History of back and abdominal surgery 6) structural injuries of the spine 7) Pregnancy or history of pregnancy in the last year 8) History of therapeutic exercise in the last 3 months

Intervention groups

The first group or the control group will receive routine physiotherapy treatment and exercises, and the second group will receive routine physiotherapy treatment along with walking forward, backward and sideways on a treadmill.

Main outcome variables

Static, dynamic balance indicators, pain, disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040466N7**

Registration date: **2023-10-09, 1402/07/17**

Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**

Update count: **0**

Registration date

2023-10-09, 1402/07/17

Registrant information

Name

Fateme Ghiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 6708

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of walking on postural reactions, pain and disability in patients with non-specific chronic low back pain

Public title

Investigating the effect of walking on postural reactions in patients with low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Years: Range:18-45, males and females Chronic back pain in the area between the twelfth rib and the rump without reference to the lower limbs, which has lasted for more than three months and has no specific cause and has caused problems in performance and physical disability and has not subsided. People with a desire to enter the study

Exclusion criteria:

History of neurological disorder Rheumatic diseases
Cancer Spinal cord lesions History of surgery Structural injuries of the spine Pregnancy History of therapeutic exercise in the last 3 months

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the number of patients in each group, the particular sort of treatment (The electrotherapy treatment group and routine physiotherapy exercises or the electrotherapy routine treatment group includes physiotherapy along with walking exercises on the treadmill, including walking forward, walking backwards and walking sideways) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the first session of the patient treatment and the patient's treatment technique is selected based on that. If any of the patients is omitted from the study, one envelope related to the excluded patient treatment group will be replaced and they will be mixed again.

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 Zahedan University of Medical Sciences

Street address

Dr. Hesabi Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2023-10-08, 1402/07/16

Ethics committee reference number

IR.ZAUMS.REC.1402.255

Health conditions studied

1

Description of health condition studied

Chronic non-specific low back pain

ICD-10 code

M54.9

ICD-10 code description

Dorsalgia, unspecified

Primary outcomes

1

Description

1-Overall static stability index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

2

Description

Anterior-posterior static stability index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

3

Description

Internal and external static stability index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

4

Description

Overall dynamic stability index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

5

Description

Anterior-posterior dynamic stability index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

6

Description

Stability index of internal and external dynamics

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Biodex device

7

Description

Pain intensity index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

VAS questionnaire

8

Description

Disability severity index

Timepoint

The beginning of the study (before the start of the intervention) and the end of the 6-week treatment period

Method of measurement

Oswestry Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Electrotherapy includes 20 minutes of TENS, 20 minutes of infrared, stretching and

strengthening exercises, and active free exercise for lumbosacral. The total duration of a physiotherapy session will be one hour. It will last three days a week for six weeks.

Category

Rehabilitation

2

Description

Intervention group: In addition to the treadmill walking routine, it will include walking forward, walking backward, and walking sideways. First, the exercise period will start with ten minutes of walking forward. Then, every week, walking backwards and walking to the sides will be added for five minutes, so that in the fifth week of the research, the total time of walking on the treadmill will be thirty-five minutes and will be done in all directions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjo Moghadam Clinic

Full name of responsible person

Keyvan Mirzabakhri

Street address

Razmejo Moghadam Laboratory, Ayatoallah Kafami St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakshaei

Street address

Zahedan University of Medical Sciences, Dr.Hesabi sq.

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Ghiasi

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Fateme Ghiasi

Position

Assistance professor

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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