

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the effects of lumbar manipulation on pain, disability and selective biomechanical parameters in athletes with low back pain based on Delitto classification subgroup of manipulation and other subgroups

Protocol summary

Study aim

Comparison of the effect of manipulation on pain, functional disability and some biomechanical parameters in athletes with low back pain based on Delitto classification subgroup of manipulation and other subgroups

Design

Clinical trial, community base, double-blind, follow up after one month Group1: 23 athletes with low back pain, having criteria described by manipulation subgroup of Delitto classification system Group2: 23 athletes with low back pain, have no criteria described by manipulation subgroup of Delitto classification system

Settings and conduct

People with low back pain enter the study after preliminary assessment; The study will be conducted in the Faculty of Rehabilitation sciences, Shiraz University of Medical Sciences; Patient and assessor are both unaware of the grouping; Manipulation will be applied in three sessions; The outcome measures will be evaluated before and after treatment

Participants/Inclusion and exclusion criteria

Inclusion: Age range 18 to 35 years (both groups) Practice athletic training at least 3 times a week for 2 hours each time (both groups) Having 4 of 5 criteria described by manipulation subgroup of Delitto classification system (Delitto group) People who have low back pain but have not the criteria described by Delitto classification system (non-Delitto group) No contraindication for lumbar manipulation (non-Delitto group) Exclusion: Physiotherapy and manual therapy over the past 3 months Taking analgesic and inflammatory drugs within past 48 hours Surgical history in lumbar and pelvis Spinal abnormalities Corticosteroids injection within the past 1 month Pressure on the lumbar nerve roots Diabetes, rheumatoid arthritis, neuropathy

Intervention groups

Manipulation will be applied in both low back pain groups

Main outcome variables

Lumbar lordosis; Pain; Functional disability; Balance; Proprioception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181119041700N1**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **prospective**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

amirhossein akbarpur

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3727 1723

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amirhosseinakbarpur@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of lumbar manipulation on pain, disability and selective biomechanical parameters in athletes with low back pain based on Delitto classification subgroup of manipulation and other subgroups

Public title
The effect of manipulation on athletes with low back pain in Delitto and non-Delitto gorups

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 18 to 35 years (for both groups) People who practice athletic training at least three times a week for two hours each time (for both groups) Haveing 4 of 5 criteria described by manipulation subgroup of Delitto classification system (for Delitto group) People who have low back pain but have not the criteria described by manipulation subgroup of Delitto classification system (for non-Delitto group) People who have no contrandication for lumbar manipulation (for non-Delitto group)
Exclusion criteria:
Physiotherapy and manual therapy over the past 3 months Taking analgesic and inflammatory drugs within past 48 hours Pressure on the lumbar nerve roots Surgical history in lumbar and pelvis Spinal abnormalities Corticosteroids injection within the past 1 month Diabetes, rheumatoid arthritis, neuropathy History of neurological disorders or central nervous system disease

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient will be unaware of the group that located in
The researcher who will do the assessments will be unaware of the groups

Placebo
Not used

Assignment

Other

Other design features
The low back pain patients who have 4 of 5 criteria described by manipulation subgroup of Delitto classification system will be allocated to the Delitto group and the low back pain patients who have not these criteria will be allocated to the non-Delitto group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

7th floor, Shiraz University of Medical Sciences, Zand Ave.

City

Shiraz

Province

Fars

Postal code

71345-1733

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.SUMS.REC.1397.517

Health conditions studied

1

Description of health condition studied

Low back pain based on the criteria of manipulation subgroup of Delitto and Low back pain based on the non-Delitto criteria

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain

Timepoint

Before, after and one month after treatment

Method of measurement

Numeric rating scale

2

Description

Functional disability

Timepoint

Before and one month after treatment

Method of measurement

Functional disability level questionnaire

Secondary outcomes

1

Description

Lumbar lordosis

Timepoint

Before and after treatment

Method of measurement

Flexible ruler

2

Description

Joint proprioception

Timepoint

Before and after treatment

Method of measurement

Inclinometer

3

Description

Balance

Timepoint

Before and after treatment

Method of measurement

"Single leg stance" test and "timed up and go" test

Intervention groups

1

Description

Group 1: 23 athletes with low back pain who have 4 of 5 criteria of Delitto manipulation subgroup. The interventions will be the "lumbar manipulation". The manipulation will be applied on the patient in the side-lying position during 3 sessions.

Category

Rehabilitation

2

Description

Group 2: 23 athletes with low back pain who have not the criteria of Delitto manipulation subgroup. The interventions will be the "lumbar manipulation". The manipulation will be applied on the patient in the side-lying position during 3 sessions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz medical clinics

Full name of responsible person

Amirhossein Akbarpur

Street address

School of Rehabilitation Sciences, 1st Abiverdi, Chamran Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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7th floor, Shiraz University of Medical Sciences, Zand Ave.

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71345-1978

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Amirhossein Akbarpur

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Not applicable

Data Dictionary

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

Title and more details about the data/document

The results will be published as an article in the research international journals

When the data will become available and for how long

In the next one to two years

To whom data/document is available

Only people who ask the information from the main investigator

Under which criteria data/document could be used

With the permission through a written or an oral request

From where data/document is obtainable

School of Rehabilitation Sciences, Shiraz University of Medical Sciences, 1st Abiverdi, Chamran Blv., Mr Amirhossein Akbarpur, Phone number: 0098 71 36271551

What processes are involved for a request to access data/document

With a written request, they can access the library of Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Comments