

# 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)

##### Phone

+98 71 3727 1723

##### Email address

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 groups

**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) Having 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 contraindication 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

##### **City**

Shiraz

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 71 3627 1551

##### **Email**

amirhosseinakbarpur@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Younes Ghasemi

##### **Street address**

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

##### **City**

Shiraz

##### **Province**

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##### **Postal code**

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##### **Phone**

+98 71 3235 7282

##### **Email**

ghasemiy@sums.ac.ir

#### **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

**Street address**

School of Rehabilitation Sciences, 1st Abiverdi,  
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## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Amirhossein Akbarpur

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Msc student

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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**