

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effects of core stabilization exercises on multifidus and gluteus maximus muscles activity and thickness, pain and disability in subjects with nonspecific chronic low back pain

#### Protocol summary

##### Study aim

the aim of this study was to assess the effects of core stabilization exercises on multifidus and gluteus maximus muscles activity and thickness in subjects with nonspecific chronic low back pain.

##### Design

32 Subjects with non specific chronic low back pain were selected through non probability sampling method.

##### Settings and conduct

This randomized clinical trial was performed in Tavana clinic in Zahedan, in 2018 2019.

##### Participants/Inclusion and exclusion criteria

The subjects were selected based on following inclusion criteria: Age between 18 and 45, Low back pain between costal margin and gluteal fold with or without distributing in lower extremity for more than 3 months, No history of neurological disorder, Spinal surgery, Pregnancy, Lumbar spine disorder, Non mechanical low back pain. Exclusion criteria included: Another training about core stabilization exercise.

##### Intervention groups

The subjects were randomly allocated to two groups: exercise group and control group. Each of the two the two groups received their interventions for 4 weeks and 5 sessions per week. Before and after the period of the interventions, overall, thickness of muscles through ultrasound imaging and activity of muscles through electromyography method, pain and disability with visual analogue scale and Oswestry index were measured.

##### Main outcome variables

Muscles thickness; Muscles activity; Pain; Disability.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181006041251N1**

Registration date: **2019-04-30, 1398/02/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-30, 1398/02/10**

Update count: **0**

##### Registration date

2019-04-30, 1398/02/10

##### Registrant information

###### Name

Shideh Narouei

###### Name of organization / entity

Tehran university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3321 8614

###### Email address

shnarouei@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-15, 1398/01/26

##### Expected recruitment end date

2019-07-01, 1398/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of core stabilization exercises on multifidus and gluteus maximus muscles activity and thickness,

pain and disability in subjects with nonspecific chronic low back pain

### Public title

The effects of core stabilization exercises on multifidus and gluteus maximus muscles activity and thickness

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age between 18 and 45; low back pain between costal margin and gluteal fold with or without distributing in lower extremity for more than 3 months; no history of neurological disorder; spinal surgery; pregnancy; lumbar spine disorder; Non mechanical low back pain.

#### Exclusion criteria:

Another training about core stabilization exercise.

### Age

From **18 years** old to **45 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **34**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The names of subjects with inclusion criteria of this study was written on pieces of papers as nonobservable. These papers were put into a bag. Then, these papers were randomized selected with randomized draw and put into two various randomized groups.

### 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

Deputy of Research, Zahedan University of Medical Sciences, Jannat Blvd, Dr Hesabi Sq. Zahedan

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

#### Postal code

9816843463

#### Approval date

2019-04-14, 1398/01/25

#### Ethics committee reference number

IR. ZAUMS. REC. 1398.027

## 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

Muscle thickness

#### Timepoint

Before and after the period of the interventions

#### Method of measurement

Ultrasound imaging

### 2

#### Description

Muscle activity

#### Timepoint

Before and after the period of the interventions

#### Method of measurement

Electromyography

### 3

#### Description

Pain

#### Timepoint

Before and after the period of the interventions

#### Method of measurement

Visual analogue scale

### 4

#### Description

Disability

#### Timepoint

Before and after the period of the interventions

#### Method of measurement

Oswestry index

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Exercise group: This group received sixteen training during 4 consecutive weeks, five times per week, 30 minutes per session.

#### Category

Rehabilitation

### 2

#### Description

Control group: This group received electrical stimulation during 4 consecutive weeks, five times per week, 15 minutes per session.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physical therapy clinic of Tavana

##### Full name of responsible person

Shideh Narouei

##### Street address

Amiralmomenin Street, Pastor medicine building

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9813683489

##### Phone

+98 54 3321 4804

##### Email

pt\_tavana@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Dr Asghar Akbari

##### Street address

Deputy of Research, Zahedan University of Medical Sciences, Jannat Blvd., Dr. Hesabi Sq.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5715

#### Email

a.akbari@zaums.ac.ir

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Shideh Narouei

##### Position

Physiotherapist

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Sport Medicine

##### Street address

Amiralmomenin Street, Physical therapy clinic of Tavana

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9813683489

##### Phone

+98 33214804

##### Email

pt\_tavana@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Shideh Narouei

##### Position

Physiotherapist

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Rehabilitation management

**Street address**

Azadi Street, Azadi 2 Street, Building of Besharat, Unit 3

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9813683489

**Phone**

+98 21 3321 8614

**Email**

pt\_tavana@yahoo.com

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

Tehran University of Medical Sciences

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Shideh Narouei

**Position**

Physiotherapist

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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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The whole data after making people unidentifiable can be shared.

**When the data will become available and for how long**

2 months after publication of the results.

**To whom data/document is available**

Researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

All whole data is available for researchers after making the participants unidentifiable, and any other analysis on the data and any use for research and therapeutic purposes is permitted in this study.

**From where data/document is obtainable**

Dr. Shideh Narouei, Address: Clinic of Physiotherapy of Tavana, Amiralmomenini St City: zahedan Country: Iran Postal code:9813683489 Tel:+98 54 3321 4804 Email: pt\_tavana@yahoo.com

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

After receiving the message from the person requesting the application, and investigating the terms of the request at the earliest opportunity is the information required to be sent to the individual.

**Comments**

do not have