

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of core stability and suspension exercise on some EMG coordinates, beta-endorphin and functional disability in people with lumbar disc herniation

#### Protocol summary

##### Study aim

Comparison of core stability and suspension exercise on some EMG coordinates, beta-endorphin and functional disability in people with lumbar disc herniation

##### Design

A clinical trial on 45 people with two intervention groups and one control group (15 people in each group), with parallel groups, randomized

##### Settings and conduct

The present study is a randomized controlled trial on people with lumbar disc herniation in rasht city. Subjects will participated in a training course for 8 weeks. Measurement of pain, functional disability, range of motion, electromyographic data and blood samples will be performed before and after intervention .

##### Participants/Inclusion and exclusion criteria

1-Male participants with Age 25-55 years old 2-Mild to moderate lumbar pain intensity with visual analog scale 2 to 7 and severity of disc herniation with grade 1 and 2 (bulging and protrusion) 3-History of low back pain for more than 3 months 4-Not having neurological diseases, cancer, diabetes and any disease affecting on treatment process 5-Not participating in regular sports exercises 6- Not using other treatments for low back pain

##### Intervention groups

First Intervention group : Core stability exercises for 8 weeks. them as: bridging, push-up, inverted row, oblique sit-up, femur abduction, femur flexion and plank. Second Intervention group: Suspension exercises for 8 weeks which are similar to the first group in suspension model. Control group: Self-care methods at home

##### Main outcome variables

Plasma beta-endorphin, functional disability, muscle activity

#### General information

##### Reason for update

##### Acronym

EMG

##### IRCT registration information

IRCT registration number: **IRCT20191016045136N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

##### Registration date

2020-08-21, 1399/05/31

##### Registrant information

##### Name

yasser mohebbi rad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3212 4093

##### Email address

yaser.mr2003@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-08-05, 1399/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of core stability and suspension exercise on some EMG coordinates, beta-endorphin and functional disability in people with lumbar disc herniation

### Public title

Comparison of core stability and suspension exercise in people with lumbar disc herniation

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Mild to moderate lumbar pain intensity with a visual analog scale score between 2-7 and severity of disc herniation with grade 1 and 2 (bulging and protrusion) History of low back pain for more than three months Not having specific diseases such as neurological diseases, cancer, diabetes, osteoporosis, etc. Not participating in regular exercise means 3 sessions per week for at least one year Not using other treatments for low back pain during the intervention

#### Exclusion criteria:

Absences in training More than two session Dissatisfaction with continuing training Getting illness or injury during the intervention period

### Age

From **25 years** old to **55 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Restricted randomization, Individual, random allocation roll, Sequentially numbered, sealed, opaque envelopes (The names are written on a piece of paper and placed in similar envelopes. Then they are randomly placed in containers 1, 2 and 3 as a mark of 3 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 Islamic Azad University-Rasht Branch

##### Street address

Navab Tower- Navab Street- Golsar Crossroad

##### City

Rasht

##### Province

Guilan

##### Postal code

4163774654

#### Approval date

2020-06-22, 1399/04/02

#### Ethics committee reference number

IR.IAU.RASHT.REC.1399.019

## Health conditions studied

### 1

#### Description of health condition studied

Lumbar disc herniation

#### ICD-10 code

M51.26

#### ICD-10 code description

Other intervertebral disc displacement, lumbar region

## Primary outcomes

### 1

#### Description

Plasma beta endorphan

#### Timepoint

12 hours before and after intervention

#### Method of measurement

Blood sample- ELISA (Enzyme-linked immunosorbent)

### 2

#### Description

Functional disability

#### Timepoint

Before and after intervention

#### Method of measurement

Oswestry disability index

### 3

#### Description

Muscles activity

#### Timepoint

Before and after intervention

#### Method of measurement

Electromyography

## Secondary outcomes

## 1

### Description

Pain

### Timepoint

Before and after intervention

### Method of measurement

Mcgill pain questionnaire

## 2

### Description

Lumbar range of motion

### Timepoint

Before and after intervention

### Method of measurement

Modified Schöber test

## Intervention groups

## 1

### Description

First Intervention group : core stability exercises for 8 weeks, 3 sessions per week including warm-up (5 minute), exercise (40 minute) and cool down (5 minute). Exercises include bridging (5 repetitions in form of movement-hold-back with 2-3-2 seconds and 1 minute rest between repetitions), push-up (Similar to the first case), inverted row (Similar to the first case), oblique sit-up (Similar to the first case), femur abduction (Similar to the first case), femur flexion (Similar to the first case) and plank (1 repetition with 10 seconds hold). There are 1 minute rest between each workout and the next

### Category

Rehabilitation

## 2

### Description

Second Intervention group: Suspension exercises for 8 weeks, 3 sessions per week including warm-up (5 minute), exercise (40 minute) and cool down (5 minute). Exercises include suspension bridging (5 repetitions in form of movement-hold-back with 2-3-2 seconds and 1 minute rest between repetitions), suspension push-up (Similar to the first case), suspension inverted row (Similar to the first case), suspension oblique sit-up (Similar to the first case), suspension femur abduction (Similar to the first case), suspension femur flexion (Similar to the first case) and suspension plank (1 repetition with 10 seconds hold). There are 1 minute rest between each workout and the next

### Category

Rehabilitation

## 3

### Description

Control group: Self-care methods at home (Such as how to properly sit, sleep and carry and lift loads)

### Category

Behavior

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Pardis physiotherapy clinic

#### Full name of responsible person

Yasser Mohebbi Rad

#### Street address

Navab Tower, Navab Street, Golsar Crossroads

#### City

Rasht

#### Province

Guilan

#### Postal code

4163774654

#### Phone

+98 13 3212 4093

#### Email

yaser.mr2003@gmail.com

#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Islamic Azad University

#### Full name of responsible person

Mohammadreza Fadaei Chafi

#### Street address

Number 3, Golestan Bulding, Siadati Alley, Mellat Street,

#### City

Rasht

#### Province

Guilan

#### Postal code

4144643199

#### Phone

+98 13 3211 7387

#### Email

mfadaei2000@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Islamic Azad University- Rasht Branch

#### Proportion provided by this source

1

#### Public or private sector

Private

#### 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**

Islamic Azad University

**Full name of responsible person**

Yasser Mohebbi Rad

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Navab Tower, Navab Street, Golsar Crossroads

**City**

Rasht

**Province**

Guilan

**Postal code**

4163774654

**Phone**

+98 31 3212 4093

**Fax**

**Email**

yaser.mr2003@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Yasser Mohebbi Rad

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Navab Tower, Navab Street, Golsar Crossroads

**City**

Rasht

**Province**

Guilan

**Postal code**

4163774654

**Phone**

+98 31 3212 4093

**Fax**

**Email**

yaser.mr2003@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Yasser Mohebbi Rad

**Position**

Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Navab Tower, Navab Street, Golsar Crossroads

**City**

Rasht

**Province**

Guilan

**Postal code**

4163774654

**Phone**

+98 31 3212 4093

**Fax**

**Email**

yaser.mr2003@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Part of the data, such as primary and secondary outcome information is shared

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

Access starts 12 months after the results are published

**To whom data/document is available**

Researchers from academic institutions and medical therapists

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

There are no other conditions

**From where data/document is obtainable**

Send request to email yaser.mr2003@gmail.com

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

First, the official request should be sent to the e-mail and after confirmation, other documents such as ID card and university confirmation documents should be sent. Data

documents will be sent in less than a month after

verification  
**Comments**