

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Effectiveness of core stability Training of Lumbar Muscles in brucellosis Patients with Acute Low Back Pain

#### Protocol summary

##### Study aim

Improvement of back pain in brucellosis patients with low back pain with using core stability training

##### Design

A randomized controlled clinical trial with parallel groups including exercise therapy group and control group without specific exercises

##### Settings and conduct

Patients with brucellosis in the ward and infectious disease ward of Valiasr Hospital in Zanjan After randomization, they will be divided into experimental and control groups. In the exercise group, patients will be trained to exercise pelvic girdle and abdominal strength exercises. In the control group only the relevant indicators in the study qualifications will be evaluated reliably and will do no exercise.

##### Participants/Inclusion and exclusion criteria

Patients with brucellosis with acute low back pain informed consent and lack of known chronic diseases

##### Intervention groups

Patients will be randomly divided into two groups: Intervention or Exercise Group: Abdominal and Lumbar Endurance Muscle Tests will be removed at the beginning of the study. And then, during admission to the respective training sessions, they will perform three times daily for 10 minutes each time. The initial tests will be repeated two weeks later. The second group will consist of patients who will only receive abdominal and lumbar endurance tests at the beginning of the study and will not receive treatment again after the initial two weeks of follow-up.

##### Main outcome variables

Severity of back pain in patients with brucellosis  
Endurance of lumbar and abdominal muscles in patients with brucellosis

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190225042842N1**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **retrospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

##### Registration date

2019-09-30, 1398/07/08

##### Registrant information

###### Name

leila rezaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8823 0523

###### Email address

leila.rezaei.sport@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

2019-06-22, 1398/04/01

##### Actual recruitment end date

2019-07-06, 1398/04/15

##### Trial completion date

2019-07-27, 1398/05/05

##### Scientific title

Effectiveness of core stability Training of Lumbar Muscles in brucellosis Patients with Acute Low Back Pain

**Public title**

Effectiveness of core stability Training of Lumbar Muscles in patients with Acute Low Back Pain

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Written and informed consent to the study process  
Diagnosis of brucellosis based on history and laboratory examination  
Ages 15 to 75 years  
Acute low back pain (LBP less than three weeks old)

**Exclusion criteria:**

History of surgery in the spinal cord  
Cancer  
History of fractures and discopathy in the spine  
Infectious disease or renal, pulmonary, cardiac and hepatic diseases  
Severe psychiatric illness  
Alcohol consumption of psychotropic drugs

**Age**

From **15 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

Actual sample size reached: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, a sample size of approximately 24 people, 12 balls for intervention group A and 12 balls for intervention group B were placed in a lottery container and then the balls were randomly removed from the container without replacement and the resulting sequence was recorded.

**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 Zanjan University of Medical Sciences

**Street address**

Azadi blvd.zanjan

**City**

zanjan

**Province**

Zanjan

**Postal code**

13191-45156

**Approval date**

2019-07-06, 1398/04/15

**Ethics committee reference number**

IR.ZUMS.REC.1398.093

**Health conditions studied****1****Description of health condition studied**

Low back pain in patients with brucellosis

**ICD-10 code**

A23.0

**ICD-10 code description**

Brucellosis due to Brucella melitensis

**Primary outcomes****1****Description**

The amount of pain

**Timepoint**

Measurement of pain at baseline and after 2 weeks of treatment

**Method of measurement**

Pain Questionnaire(Visual Analogue Score)

**2****Description**

lumbar muscles endurance

**Timepoint**

Measurement of lumbar muscle endurance at baseline and 2 weeks after treatment initiation

**Method of measurement**

The number of lumbar muscle contractions based on the Sorensen test

**3****Description**

Abdominal muscles endurance

**Timepoint**

Abdominal muscle endurance measurement at baseline and 2 weeks after initiation of treatment

**Method of measurement**

Sit up test(crunch test)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Stabilization Exercise Group Exercise Program: In this group, the sample will perform training sessions in 42 sessions under the supervision of a sports medicine specialist and physical education expert, in 3 sessions per day for 2 weeks in each session for approximately 10 minutes. At the beginning of each treatment session, a warm-up (about 5 minutes) will consist of light stretching exercises and each exercise will be repeated in 3 sets. The overload and incremental increase of each exercise will be monitored and determined with respect to the correct execution and pressure of the exercise in the previous session. The goal is to maximize the repetitions of each exercise per set. The major emphasis will be on the multifidus and transverse abdominal muscles. All movements should be performed ten times in painless range. Ten minutes in the morning, ten minutes in the afternoon and ten minutes in the evening. Intervention group: Patients with low back pain will undergo core stability training called core stability training. 2 to 3 times and 10 times each. Repeat the first move: the person pulls the legs up and down in a cramped position while the legs are rotating. The second move: back and forth The knee lifts the knee and lower limb to the bridging position, pausing to tolerate the bridge position and then slowly lowering and then repeating the move Third Movement: In supine position, with elbows resting on the ground, lift the servo upward for six seconds and then rest for three seconds. Repeat this motion. Fourth move: Sleeping behind each foot with the help of hands. The abdomen closes and stretches for six seconds, then lifts the opposite leg. Fifth move: The person is placed in a four-legged position, with the elbow flexing upward and downward, and the elbow flexion at least shrinks and the elbow returns to normal. Sixth Movement: While lying on his back while knee flexing, his abdomen is contracted into the abdomen, adhering repeatedly to the ground, maintaining the contraction for six seconds, and the movements are repeated.

**Category**

Rehabilitation

**2**

**Description**

Control group: Patients with acute low back pain who do not receive exercise

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Infectious diseases ward Valiasr hospital zanzan city

**Full name of responsible person**

Leila Rezaei

**Street address**

Valiasr Medical Center;Valiasr Square,Sheikh Fazlollah Noori Highway,Zanzan

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**Province**

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**Phone**

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**Email**

valiasr@zums.ac.ir

**Web page address**

http://zums.ac.ir/page/808

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Ali niazi

**Street address**

Central University Organization.Shohada Hesarak Boulevard.University Square.End of Shahid Sattari Highway (North).Tehran

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Tehran

**Province**

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ali.niazi@gmail.com

**Web page address**

https://rvp.iau.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Leila rezaei

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Islamic Azad University

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**Latest degree**

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**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Leila rezaei

**Position**

Nurse

**Latest degree**

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### Other areas of specialty/work

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### Province

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### Postal code

1464764319

### Phone

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### Email

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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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

Patients' information includes family name and confidential registration and access to researcher and related researcher But the information extracted and the results of the study will be published in the form of a master's thesis and the resulting papers

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

Access will usually be available to clients and undergraduates at the University Central Library after completion of the defense and dissertation procedures. Estimated time is the end of 2019 and the article extracted from it is likely to be available in related journals in 2020

### To whom data/document is available

Undergraduate Students of Tehran Azad University Central Branch

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

For use in academic and hospital research

### From where data/document is obtainable

Islamic Azad University Central Library Web site

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

After registration at Azad University Central Library, applicants can access the full text or abstract of the dissertation and related article if they are a student of Azad University

### Comments