

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 zanjan city

Full name of responsible person

Leila Rezaei

Street address

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

City

Zanjan

Province

Zanjan

Postal code

45157-77978

Phone

+98 24 3377 0801

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

City

Tehran

Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

Phone

+98 21 4735 3702

Email

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

Street address

No. 5, Pamcal Alley, etaati strteet, marzdaran town

City

Tehran

Province

Tehran

Postal code

1464764319

Phone

+98 21 8823 0532

Email

leila.rezaei.sport@gmail

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Leila rezaei

Position

پرستار

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 5, Pamcal Alley, etaati street, marzdaran town

City

Tehran

Province

Tehran

Postal code

1464764319

Phone

+98 21 8823 0532

Email

Leila.rezaei.sport@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Leila rezaei

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 5, Pamcal Alley, etaati street, marzdaran town

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Province

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Postal code

1464764319

Phone

+98 21 8823 0532

Email

Leila.rezaei.sport@gmail.com

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