Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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 discopaty 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

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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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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
Ŝtudent

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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