

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of zinc supplementation on clinical status, inflammatory factors, and oxidative stress biomarkers in patients with brucellosis

Protocol summary

Study aim

The aim of this study is to determine the effects of zinc supplementation on clinical outcomes and biomarkers of oxidative stress and inflammation in patients with brucellosis.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive zinc supplement (n=40) or placebo (n=40). The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Settings and conduct

Among patients with brucellosis referred to the Infectious diseases clinic at Shahid Beheshti hospital affiliated to Kashan University of Medical Sciences, 80 patients will be selected according to inclusion and exclusion criteria. Patients and researchers will not know the type of intervention. Supplements and placebos are similar. Blood samples will be taken at baseline and 8 weeks after the intervention. Intervention period: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-80 years, diagnosed with brucellosis. Exclusion criteria: Patients who are receiving any immunosuppressive drugs, people diagnosed with the acquired immunosuppressive disease, taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment.

Intervention groups

Intervention group: 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 8 weeks orally. Control group: Placebo (Donyaye Behdasht, Tehran, Iran), daily for 8 weeks orally.

Main outcome variables

Outcomes: Serum hs-CRP (primary outcome) and clinical outcomes, biomarkers of oxidative stress (secondary outcomes) will be quantified.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N70**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **retrospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-07, 1397/12/16

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of zinc supplementation on clinical status, inflammatory factors, and oxidative stress biomarkers in patients with brucellosis

Public title

The effects of zinc supplementation in the treatment of patients with brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with brucellosis Individuals aged 18-80 years

Exclusion criteria:

Taking any antioxidant and/or anti-inflammatory supplements within 3 months prior to the enrollment. Patients diagnosed with acquired immunosuppressive disease Patients who are receiving any immunosuppressive drugs.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 80 by a random number generator (<https://stattrek.com/statistics/random-number-generator.aspx>) and patients will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Infectious diseases clinic of Shahid Beheshti Hospital, affiliated to Kashan University of Medical Science, who is not involved in the trial and not aware of random sequences, will assign the participants to intervention groups. Supplements and placebos are in the same packaging at the Donyayeh Behdasht pharmaceutical company. Only the code is written on the packages. Patients and researchers will not know the type of intervention. After analyzing the data, packet codes will be decoded. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.002

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description

Serum hs-CRP levels

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

Fever duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

2

Description

Chills duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

3

Description

Sweating duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

4

Description

Arthritis duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

5

Description

Arthralgia duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

After intervention

6

Description

Myalgia duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

7

Description

Anorexia duration

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Checklist

8

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Glutathione

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: 30 mg elemental zinc (Donyayeh Behdasht, Tehran, Iran) daily for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Donyayeh Behdasht, Tehran, Iran), daily for 8 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Infectious diseases Clinic of Shahid Beheshti hospital of Kashan

Full name of responsible person

Dr. Hamid Niaparast

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

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8115187159
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
Street address
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City
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Postal code
8115187159
Phone
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Email
banafshe-h@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamid Niaparast
Position
Academic Researcher
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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