

# 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**

Isfahan  
**Postal code**  
8115187159  
**Phone**  
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**Email**  
niaparast.h@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Dr. Hamidreza Banafshe  
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Ghotbe Ravandi Boulevard, Kashan  
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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

#### Contact

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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