

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of zinc supplementation versus control group on cellular immunity, treatment, and relapse of brucellosis: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of zinc supplementation versus control group on cellular immunity, treatment, and relapse of brucellosis

Design

This is a single-blind randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with acute brucellosis referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single-blinded so that patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 15 to 60 years, Acute brucellosis
Exclusion criteria: Pregnancy, History of brucellosis, Complicated brucellosis, Chronic diseases such as cardiovascular disease, anemia, bone carcinoma, Concurrent with AIDS, A history of collagen vascular disease, History of zinc use

Intervention groups

Intervention group: Routine treatment brucellosis plus Zinc gluconate tablet (manufactured by Darukadeh Pharmaceutical Co.) 30 mg daily for 8 weeks
Control group: Routine treatment brucellosis

Main outcome variables

Primary outcome: Clinical symptoms, treatment of the disease, relapse of the disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N332**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation versus control group on cellular immunity, treatment, and relapse of brucellosis:

a single-blind randomized clinical trial

Public title
Effect of zinc supplementation versus control group on cellular immunity, treatment and relapse of brucellosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 15 to 60 years, Acute brucellosis
Exclusion criteria:
Pregnancy, History of brucellosis, Complicated brucellosis, Chronic diseases such as cardiovascular disease, anemia, bone carcinoma, Concurrent with AIDS, A history of collagen vascular disease, A history of zinc use

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The drugs will be given in coded envelopes. Therefore, patients will be unaware of the type of intervention. Thus, the trial will be run as single-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2019-12-21, 1398/09/30

Ethics committee reference number
IR.UMSHA.REC.1398.767

Health conditions studied

1

Description of health condition studied

Brucellosis

ICD-10 code

A23

ICD-10 code description

Brucellosis

Primary outcomes

1

Description

Clinical symptoms

Timepoint

Before the intervention and 1 and 2 months later

Method of measurement

By taking history and physical examination

2

Description

Treatment of the disease

Timepoint

1 and 2 months after the intervention

Method of measurement

by using 2ME test

3

Description

Relapse of the disease

Timepoint

6 months after the intervention

Method of measurement

by using 2ME test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment brucellosis plus Zinc gluconate tablet (manufactured by Darukadeh Pharmaciutical Co.) 30 mg daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Routine treatment brucellosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr. Fariba Keramat

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

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6517838695

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+98 81 3827 4184

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faribakeramat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Fariba Keramat

Position

Specialist in Infectious Diseases

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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