

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effects of probiotics supplementation in the treatment of children with brucellosis

Protocol summary

Study aim

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

Design

Clinical trial with placebo group, Parallel groups, double-blind, randomized

Settings and conduct

Among children with brucellosis referred to the pediatric clinic at Shahid Beheshti hospital affiliated to Kashan University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Children, their parents, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Blood samples will be taken at baseline and 8 weeks after the intervention. Intervention period: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 8-15 years, diagnosed with brucellosis. Exclusion criteria: Patients who are receiving any immunosuppressive drugs, children 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: Probiotic capsule (Zisttakhmir Co., Iran) including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily for 8 weeks orally. Control group: Placebo capsule (Barij essence, Kashan, 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

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N65**

Registration date: **2019-10-14, 1398/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **1**

Registration date

2019-10-14, 1398/07/22

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-03, 1398/06/12

Expected recruitment end date

2022-02-17, 1400/11/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of probiotics supplementation in the treatment of children with brucellosis

Public title

Probiotics and brucellosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children diagnosed with brucellosis Children aged 8-15 years

Exclusion criteria:

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

Age

From **8 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 40 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 Pediatric 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.

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

2019-09-02, 1398/06/11

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1398.044

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

After intervention

Method of measurement

Checklist

2

Description

Chills duration

Timepoint

After intervention

Method of measurement

Checklist

3

Description

Sweating duration

Timepoint

After intervention

Method of measurement

Checklist

4

Description

Musculoskeletal pain

Timepoint

After intervention

Method of measurement

Checklist

5

Description

Anorexia duration

Timepoint

After intervention

Method of measurement

Checklist

6

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

8

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: Probiotic capsule (Zisttakhmir Co., Iran) including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (Barij essence, Kashan, Iran), daily for 8 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Clinic of Shahid Beheshti hospital of Kashan

Full name of responsible person

Dr. Mohammad Reza Sharif

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Ghotbe Ravandi Boulevard, Kashan

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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

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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

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. Mohammad Reza Sharif

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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