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)

Phone
+98 31 5546 3378

Email address
ostadmohammadi-vr@kaums.ac.ir

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
Isfehan
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5562 0608
Email
mrsharifmd@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafshe
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5562 0608
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. Mohammad Reza Sharif
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

Person responsible for scientific 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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

Person responsible for updating data

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
Street address
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City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 0026
Email
mrsharifmd@yahoo.com

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