Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on metabolic profiles in patients with rheumatoid arthritis

Protocol summary

Study aim
The aim of this study is to determine the effects of probiotic supplementation on metabolic profiles in patients with rheumatoid arthritis.

Design
Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct
Population and sample size: 60 patients with rheumatoid arthritis of eligible and referred to internal medicine and rheumatology affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with rheumatoid arthritis and aged 25 to 70 years. Exclusion criteria: Chronic renal failure, renal tubular acidosis or pancreatitis, patients likely to be started on biological agents, pregnant or lactating women, patients who are unable to read numbers and/or unable to mark the pain scale, patients unlikely to come for follow-up in the following 3 months.

Intervention groups
Intervention: Patients will be assigned to receive either probiotic supplements (intervention group: n=30), placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 8-wk intervention. Start and end date of intervention: 2 months.

Main outcome variables
Outcomes: Inflammatory factors and DAS-28 (primary outcomes), markers of insulin metabolism, lipid profiles and biomarkers of oxidative stress (secondry outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201511015623N58**
Registration date: **2015-11-20, 1394/08/29**
Registration timing: **retrospective**

Last update: **2019-10-06, 1398/07/14**
Update count: **1**

Registration date
2015-11-20, 1394/08/29

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kashan University of Medical Sciences

Expected recruitment start date
2015-09-29, 1394/07/07

Expected recruitment end date
2015-10-20, 1394/07/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic supplementation compared with the placebo on metabolic profiles in patients with rheumatoid arthritis

Public title
Effect of supplementation in treatment of patients with rheumatoid arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with rheumatoid arthritis Aged 25 to 70 years
Exclusion criteria:
Chronic renal failure Renal tubular acidosis or pancreatitis Patients likely to be started on biological agents Pregnant or lactating women Patients who are unable to read numbers and/or unable to mark the pain scale Patients unlikely to come for follow-up in the following 3 months
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take probiotic supplements (n=30) or the standard diet (n=30). Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Kashan University of Medical Sciences
City
Kashan
Province
Isfehan
Postal code
8814187159
Approval date
2015-09-28, 1394/07/06
Ethics committee reference number
IR.Kaums.REC.1394.82

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis
ICD-10 code
M00.2
ICD-10 code description
Other streptococcal arthritis and polyarthritis

Primary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Elisa kit

2

Description
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
DAS-28
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Sum scores

Secondary outcomes

1

Description
Insulin
Timepoint

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

Method of measurement

Elisa kit

2

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Insulin resistance

Timepoint

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

Method of measurement

Elisa kit

8

Description

Fasting blood sugar

Timepoint

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

Method of measurement

Enzymatic kit

9

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Probiotic capsule containing four strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g), daily, for 8 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Probiotic placebo capsule, daily, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Internal medicine and rheumatology

Full name of responsible person

Zatollah Asemi

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Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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1771844351
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hamidi_gh@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, 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
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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Person responsible for updating data

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Web page address

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