

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 (secondary 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3570

###### Email address

asemi\_z@kaums.ac.ir

##### 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

Isfahan

#### 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 (2×10<sup>9</sup> CFU/g), Lactobacillus casei (2×10<sup>9</sup> CFU/g) and Bifidobacterium bifidum (2×10<sup>9</sup> 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

**Street address**

Shahid Rajaei Avenue, Kashan

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Kashan

**Province**

Isfahan

**Postal code**

1771844351

**Phone**

+98 31 5546 3378

**Email**

asemi-z@yahoo.com

## 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

**Street address**

Kashan University of Medical Sciences

**City**

Kashan

**Province**

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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**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

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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