

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Clinical trial of the effect of synbiotic 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 synbiotic supplementation on metabolic profiles in patients with rheumatoid arthritis.

Design

Study design: randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive synbiotic supplement (n=27) or placebo (n=27).

Settings and conduct

Among with rheumatoid arthritis patients referred to Shahid Beheshti Clinic, 54 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Fasting blood samples will be taken at baseline and 8 weeks after the intervention. At the beginning and the end of the intervention: 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with rheumatoid arthritis and aged 25 to 70 years. Exclusion criteria: Patients who have chronic renal failure, pregnant or lactating women, symptoms or personal history of cardiovascular disease, diabetes mellitus, the consumption of antihyperglycemic agents, patients unlikely to come for follow-up in the following 3 months and patients who are unable to read numbers and/or unable to mark the pain scale, taking probiotics, synbiotics, antioxidant and/or anti-inflammatory supplements, taking antibiotics.

Intervention groups

Intervention group: Synbiotic supplements (Tak Gen Zist Pharmaceutical Company, Tehran, Iran), one capsule for 8 weeks orally. Control group: placebo (Tak Gen Zist Pharmaceutical Company, Tehran, Iran), one capsule for 8 weeks orally.

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: **IRCT201611165623N94**

Registration date: **2016-11-18, 1395/08/28**

Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **1**

Registration date

2016-11-18, 1395/08/28

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

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2016-08-08, 1395/05/18

Expected recruitment end date

2016-09-08, 1395/06/18

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of synbiotic 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:
 Patients who had chronic renal failure Pregnant Lactating women Symptoms or personal history of cardiovascular disease, diabetes mellitus The consumption of antihyperglycemic agents Patients unlikely to come for follow-up in the following 3 months Patients who are unable to read numbers and/or unable to mark the pain scale Taking probiotics, synbiotics, antioxidant and/or anti-inflammatory supplements Taking antibiotics

Age
From **25 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after balanced randomisation, subjects will be allocated into two groups to receive supplement or placebo. 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
Random assignment will be done by the use of computer-generated random numbers.

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

8115187159

Approval date

2016-08-07, 1395/05/17

Ethics committee reference number

IR.Kaums.REC.1395.46

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**

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

3**Description**

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

4**Description**

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

5**Description**

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

6**Description**

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

7**Description**

HDL

Timepoint

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

Method of measurement

Enzymatic kit

8**Description**

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

9**Description**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

Intervention groups**1****Description**

Intervention group: Synbiotic capsule containing three strains of *Lactobacillus acidophilus* (2×10^9 CFU/g), *Lactobacillus casei* (2×10^9 CFU/g) and *Bifidobacterium bifidum* (2×10^9 CFU/g), and 0.8 g inulin (Tak Gen Zist, Tehran, Iran), once a day, for 8 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo (Tak Gen Zist, Tehran, Iran), once a day, for 8 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Shahid Beheshti Clinic
Full name of responsible person
Zatollah Asemi
Street address
Ghotbe Ravandi Boulevard, 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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Ghotbe Ravandi Boulevard, Kashan
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hamidi-gh@kaumas.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
Associate professor
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Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Other areas of specialty/work

Nutrition

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Fax**Email**

asemi_r@yahoo.com

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable