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 (secondry 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

Isfehan

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 (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g), and 0.8 g inulin (Tak Gen Zist, Tehran, Iran), once a day, for 8 weeks orally.
Category
Treatment - Drugs

2

Description
Conrol 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

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5554 0026

Email
asemi_r@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
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5554 2999

Email
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

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Email
asemi_r@yahoo.com

Person responsible for scientific 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

Street address
Ghotbe Ravandi Boulevard, Kashan

City
Kashan

Province
Isfehan

Postal code
8115187159

Phone
+98 31 5546 3378

Fax

Email
asemi_r@yahoo.com

Web page address

Person responsible for updating data

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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
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