

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effects of probiotic supplementation on oxidative indices in women with rheumatoid arthritis: a randomized controlled trial

Protocol summary

Summary

The present study is a double-blind, placebo-controlled, randomized trial to investigate the effect of probiotic supplementation on oxidative indices in women with rheumatoid arthritis. Sixty patients attending the rheumatology clinic of Sina hospital or Sheykholarayis clinic will be recruited and randomly assigned to receive either the intervention or the placebo. Inclusion criteria for the patients will be: 1) Patients diagnosed with rheumatoid arthritis, based on ACR criteria; 2) Having inactive to moderate rheumatoid arthritis; 3) Under treatment with DMARDs (Methotrexate, Hydroxychloroquine and Prednisolone less than 10 milligrams per day) and not receiving NSAIDs or cytokine inhibitors; 4) Stable medication for at least 3 month prior to the interventions; 5) Having body mass index (BMI) less than 40; 6) Willing to participate in the study; 7) Ages between 20 and 80. Exclusion criteria will include: 1) Pregnant and lactating women; 2) Hormone therapy or receiving oral contraceptives; 3) Having diabetes mellitus, thyroid disorders, kidney or hepatic diseases or Cushing's syndrome; 4) Having inflammatory bowel disease or other inflammatory disorders; 5) Having digestive tract disorders or lactose intolerance; 6) Taking antioxidant, vitamin, fiber or omega-3 supplements 3 weeks prior to the interventions; 7) Using antibiotics a month prior to the interventions; 8) Being on a weight reduction diet; 9) Smoking or being exposed to cigarette smoke; 10) Using other probiotic products. The intervention group will receive one 250 milligram capsule containing 10(10) colony forming unit (CFU) *Lactobacillus casei* each day, for 8 weeks; the other group will take one placebo capsule a day for the same period of time. At baseline and at the endpoint of the study, weight and height will be measured and BMI will be calculated; physical activity and psychological stress of the patients will be assessed using the relevant questionnaires and dietary intake of the participants will be evaluated by one 24 hour dietary recall questionnaire

and 3 dietary record questionnaires. The level of malondialdehyde and antioxidant enzymes including catalase, superoxide dismutase and glutathione peroxidase, as well as serum total antioxidant capacity will be measured using the appropriate techniques at baseline and endpoint of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207024105N10**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-08-31, 1391/06/10

Expected recruitment end date

2012-10-31, 1391/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of probiotic supplementation on oxidative indices in women with rheumatoid arthritis: a randomized controlled trial

Public title

The effects of probiotic supplementation on oxidative indices in women with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Patients diagnosed with rheumatoid arthritis, based on ACR criteria; 2) Having inactive to moderate rheumatoid arthritis; 3) Under treatment with DMARDs (Methotrexate, Hydroxychloroquine and Prednisolone less than 10 milligrams per day) and not receiving NSAIDs or cytokine inhibitors; 4) Stable medication for at least 3 month prior to the interventions; 5) Having body mass index (BMI) less than 40; 6) Willing to participate in the study; 7) Ages between 20 and 80. Exclusion criteria: 1) Pregnant and lactating women; 2) Hormone therapy or receiving oral contraceptives; 3) Having diabetes mellitus, thyroid disorders, kidney or hepatic diseases or Cushing's syndrome; 4) Having inflammatory bowel disease or other inflammatory disorders; 5) Having digestive tract disorders or lactose intolerance; 6) Taking antioxidant, vitamin, fiber or omega-3 supplements 3 weeks prior to the interventions; 7) Using antibiotics a month prior to the interventions; 8) Being on a weight reduction diet; 9) Smoking or being exposed to cigarette smoke; 10) Using other probiotic products.

Age

From **20 years** old to **80 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad Avenue

City

Tabriz

Postal code**Approval date**

2012-06-25, 1391/04/05

Ethics committee reference number

9150

Health conditions studied**1****Description of health condition studied**

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes**1****Description**

Malondialdehyde

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

2**Description**

Catalase

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

3**Description**

Superoxide dismutase

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Glutathione peroxidase

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Serum total antioxidant capacity

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Calculation based on the measured weight and height

2

Description

Calorie and nutrient intake

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

One 24 hour dietary recall questionnaire and three dietary record questionnaires

Intervention groups

1

Description

One 250 milligram capsule containing 10(10) colony forming unit (CFU) Lactobacillus.casei each day, for 8 weeks

Category

Treatment - Drugs

2

Description

One daily 250 milligram capsule not containing the probiotic bacteria for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sina hospital

Full name of responsible person**Street address****City**

Tabriz

2

Recruitment center**Name of recruitment center**

Sheykholyayis Clinic

Full name of responsible person**Street address****City**

Tabriz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

Street address

Golbad Street

City

Tabriz

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, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Elnaz Vaghef Mehrabany

Position

MSc student in nutrition sciences

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Elnaz Vaghef Mehrabany

Position

MSc student in nutrition sciences