Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The effect of probiotic supplementation on lipid profile and arylesterase activity of paraoxonase enzyme in women with rheumatoid arthritis

Protocol summary

Summary

The present study is a double-blind, placebo-controlled, randomized trial to investigate the effect of probiotic supplementation on lipid profile in women with rheumatoid arthritis. Sixty patients attending the rheumatology clinic of Sina hospital or Sheykholrayis clinic will be recruited and randomly assigned to receive either the intervention or the placebo. Inclusion criteria for the patients will be: patients diagnosed with rheumatoid arthritis, based on ACR criteria; having inactive to moderate rheumatoid arthritis; under treatment with DMARDs (Methotrexate, Hydroxychloroquine and Prednisolone less than 10 milligrams per day) and not receiving NSAIDs or cytokine inhibitors; stable medication for at least 3 month prior to the interventions; having body mass index (BMI) less than 40; willing to participate in the study; ages between 20 and 80. Exclusion criteria will include: pregnant and lactating women; hormone therapy or receiving oral contraceptives; having diabetes mellitus, thyroid disorders, kidney or hepatic diseases or Cushing's syndrome; having inflammatory bowel disease or other inflammatory disorders; having digestive tract disorders or lactose intolerance; taking antioxidant, vitamin, fiber or omega-3 supplements 3 weeks prior to the interventions; using antibiotics a month prior to the interventions; being on a weight reduction diet; smoking or being exposed to cigarette smoke; using other probiotic products. The intervention group will receive one 250 milligram capsule containing 10 (8) 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; dietary intake of the participants will be evaluated by one 24 hour dietary recall questionnaire and 3 dietary record questionnaires. The serum level of triglyceride, total cholesterol and HDL cholesterol will be measured using commercial kits and spectrophotometry technique at baseline and endpoint of the study. Serum LDL cholesterol will be calculated using Friedewald equation. Arylesterase activity of the paraoxonase enzyme will be measured in the serum samples, using phenyl acetate and by spectrophotometry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306264105N14**
Registration date: **2013-07-10, 1392/04/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-07-10, 1392/04/19

Registrant information

Name
Beit Allah Alipour
Name of organization / entity
Health & Nutrition Faculty
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7580
Email address
alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor, Tabriz University of Medical Sciences

Expected recruitment start date
2013-08-31, 1392/06/09
Expected recruitment end date
2013-10-31, 1392/08/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of probiotic supplementation on lipid profile and arylesterase activity of paraoxonase enzyme in women with rheumatoid arthritis

Public title
The effect of probiotic supplementation on lipid profile and arylesterase activity of paraoxonase enzyme in women with rheumatoid arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients diagnosed with rheumatoid arthritis, based on ACR criteria; having inactive to moderate rheumatoid arthritis; under treatment with DMARDs (Methotrexate, Hydroxychloroquine and Prednisolone less than 10 milligrams per day) and not receiving NSAIDs or cytokine inhibitors; stable medication for at least 3 month prior to the interventions; having body mass index (BMI) less than 40; willing to participate in the study; ages between 20 and 80. Exclusion criteria: pregnant and lactating women; hormone therapy or receiving oral contraceptives; having diabetes mellitus, thyroid disorders, kidney or hepatic diseases or Cushing's syndrome; having inflammatory bowel disease or other inflammatory disorders; having digestive tract disorders or lactose intolerance; Taking antioxidant, vitamin, fiber or omega-3 supplements 3 weeks prior to the interventions; using antibiotics a month prior to the interventions; being on a weight reduction diet; smoking or being exposed to cigarette smoke; 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
2013-03-18, 1391/12/28
Ethics committee reference number
91233

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
Triglyceride
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Spectrophotometry

2

Description
Total cholesterol
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
HDL cholesterol
Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

LDL cholesterol

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Friedewald equation

5

Description

Arylesterase activity of paraoxonase enzyme

Timepoint

At baseline and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

One 250 milligram capsule containing 10 (8) 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

Fatemeh Pasha-Arbat

Street address

Between Montazeri and Hafez Street, Azadi Street

City

Tabriz

2

Recruitment center

Name of recruitment center

Sheykholrayis Polyclinic

Full name of responsible person

Dr. Sakineh-Khatoun Sharif

Street address

Across from Maralan gas station, Azadi Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice chancellor, 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

Research Vice chancellor, 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

Attar Neyshapoory Avenue, Golgasht Street

City

Tabriz

Postal code
Phone
+98 41 1335 7580
Fax
Email
vaghefe@tbzmed.ac.ir
Web page address

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
Other areas of specialty/work
Street address
Attar Neyshapoory Avenue, Golgasht Street
City
Tabriz
Postal code
Phone
+98 41 1335 7580
Fax
Email
vaghefe@tbzmed.ac.ir
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