Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of probiotic supplementation on disease activity and inflammatory biomarkers of 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 disease activity and inflammatory biomarkers 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: 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 b 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 disease activity score (DAS-28) will be calculated based on physical examination and serum hs-CRP, and visual analogue scale (VAS) will be determined by a questionnaire. The level of inflammatory biomarkers (IL-1β, IL-6, IL-10, IL-12, TNF-alpha and hs-CRP) will be measured using the appropriate techniques at baseline and endpoint of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206234105N9**
Registration date: **2012-07-02, 1391/04/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-02, 1391/04/12

Registrant information

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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 disease activity and inflammatory biomarkers of women with rheumatoid arthritis: a randomized controlled trial

Public title
The effects of probiotic supplementation on symptoms and inflammatory biomarkers 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 Ave
City
Tabriz
Postal code
Approval date
2012-06-25, 1391/04/05
Ethics committee reference number
9149

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
Disease Activity Score (DAS-28)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
calculation based on physical examination and serum hs-CRP

2

Description
hs-CRP
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Immunoturbidimetry

3

Description
TNF-alpha
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

4

Description
IL-1β
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

5

Description
IL-6
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

6

Description
IL-10
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

7

Description
IL-12
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

8

Description
Visual Analogue Scale (VAS)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Body Mass Index (BMI)
Timepoint
At baseine and after 8 weeks of intervention
Method of measurement
Calculation based on the measured weight and height

2

Description
Calori and nutrient intake
Timepoint
At baseine and after 8 weeks of intervention
Method of measurement
One 24 hour dietary recall questionnaire and three dietary record questionnaires

3

Description
Systolic blood pressure
Timepoint
At baseine and after 8 weeks of intervention
Method of measurement
Stethoscope and sphyngomanometer

4

Description
Diastolic blood pressure
Timepoint
At baseine and after 8 weeks of intervention
Method of measurement
Stethoscope and sphyngomanometer

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
Sheykholrayis 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
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Person responsible for updating data

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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