

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of probiotic cheese on inflammatory and anti-inflammatory markers, disease severity and symptoms in patients with rheumatoid arthritis

Protocol summary

Study aim

The main objective of the project: Determining the effect of probiotic cheese consumption on inflammatory, anti-inflammatory factors, symptoms and severity of the disease in patients with rheumatoid arthritis

Design

A parallel randomized clinical trial with a sample size of 40 in the present study. Participants will be stratified into different blocks. For each patient in a certain block, a matched person in terms of above mentioned variables would be placed in that block. Then, these two patients in a given block would be randomly assigned to the intervention and control groups.

Settings and conduct

Sampling for this study will be done based on the inclusion criteria in Rheumatology center in Shariati Hospital in Tehran. After selecting the participants, individuals will be divided into two groups of intervention and control based on random allocation. People in the intervention and control groups will be advised to consume 30 grams of cheese given to them daily for 12 weeks. In this double-blind study, the researcher and the participant who consuming the cheese are unaware of type of cheese. So a person out of study will distribute cheeses.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Women 20 to 60 years old with moderate to severe rheumatoid arthritis Exclusion criteria 1. Having other inflammatory diseases 2. Being pregnant or breastfeeding 3. dietary supplements consumption at least one month before the intervention 4. Receive antibiotics within 1 month before the intervention 5. Consumption of probiotic foods during the last month

Intervention groups

Participants in intervention group should receive 30 grams of probiotic cheese daily Participants in control

group should daily receive 30 grams of cheese without probiotic with a similar appearance and taste to intervention group cheese

Main outcome variables

hs-CRP; IL-6; IL-10; TNF- α ; ESR; DAS-28; HAQ-DI

General information

Reason for update

Due to corona virus pandemic, we had trouble in sampling, so we decided to postpone the date of sampling. Also, due to the low cooperation of patients to enter the study to enter sampling continues for another two months.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201120049449N1**

Registration date: **2021-02-14, 1399/11/26**

Registration timing: **prospective**

Last update: **2021-06-22, 1400/04/01**

Update count: **2**

Registration date

2021-02-14, 1399/11/26

Registrant information

Name

Farzaneh Asoudeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic cheese on inflammatory and anti-inflammatory markers, disease severity and symptoms in patients with rheumatoid arthritis

Public title

The effect of probiotic cheese consumption on the improvement of patients with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Subjects with mild to moderate RA diagnosed by a rheumatologist using the ACR (American College of Rheumatology) criteria Women aged 20–60 years Following stable drug therapy At least in the last three months BMI 25–40 kg/m²

Exclusion criteria:

Suffered from other inflammatory diseases including pancreatitis, IBD and myocarditis Pregnant or breastfeeding Tobacco or drug use Alcoholic beverages consumption Liver or kidney disorder Gastrointestinal disorders or lactose intolerance Dietary supplements consumption at least one month before the intervention Using antibiotics one month before the intervention Follow a weight loss diet over the past month Consumption of probiotic foods during the last month Acute heart disease

AgeFrom **20 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants will be stratified based on age (20 to 40 and 40 to 60 years), BMI (<30 and ≥30 kg / m²), and type of medicines (NSAIDs / DMARDs / steroids / immunosuppressive) into different blocks and will be randomly allocated to the intervention or control groups. For each patient in a certain block, a matched person in terms of above mentioned variables would be placed in

that block. Then, these two patients in a given block would be randomly assigned to the intervention and control groups. To do randomization, an identification code will be given to each eligible patient, and then, code of patients with the same age, BMI, and medication will be stated in the lottery container, and finally, patients with the same conditions will be randomly assigned to the intervention or control groups. Random allocation will be done by a person who is unaware about the aim of our study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and participant are unaware of the type of cheese (probiotic or simple) and only the distributor is aware of the type of cheese.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

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Province

Tehran

Postal code

14155-6117

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.883

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

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Serum level of high-sensitivity C-reactive protein (High-sensitivity C-reactive protein is an acute-phase protein that produced by the liver in response to inflammation)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the start)

Method of measurement

Using a special commercial kit

Secondary outcomes

1

Description

The severity of disease assessment

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the intervention)

Method of measurement

Das-28 questionnaire

2

Description

Assessment of disability related disease

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the intervention)

Method of measurement

HAQ-DI (health assessment questionnaire-disability index)

3

Description

Serum level of Interleukin 6 (Interleukin 6 is an endogenous chemical which is active in inflammation, and in B cells maturation)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the start)

Method of measurement

Using a special commercial kit

4

Description

Serum level of Interleukin 10 (Interleukin 10 is an anti-inflammatory cytokine also known as human cytokine synthesis inhibitory factor (CSIF))

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the start)

Method of measurement

Using a special commercial kit

5

Description

Serum level of Tumor necrosis factor alpha (Tumor necrosis factor alpha is an inflammatory cytokine produced by macrophages/monocytes during acute inflammation and is responsible for a diverse range of signalling events within cells, leading to necrosis or apoptosis)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the start)

Method of measurement

Using a special commercial kit

6

Description

Serum level of erythrocyte sedimentation rate (Erythrocyte sedimentation rate is a type of blood test that measures how quickly erythrocytes settle at the bottom of a test tube that contains a blood sample and indirectly measures the degree of inflammation present in the body)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (84 days after the start)

Method of measurement

Using a special commercial kit

Intervention groups

1

Description

Intervention group: 30 grams of low-salt and low-fat probiotic cheese of Pegah Company daily for 12 weeks. Once every three weeks, enough packages of probiotic cheese will be distributed among the people in the intervention group.

Category

Treatment - Other

2

Description

Control group: 30 grams of low-salt and low-fat cheese without probiotic of Pegah Company daily for 12 weeks. Once every three weeks, enough packages of cheese will be distributed among the people in the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Masoumeh Akhlaghi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Jamshidi

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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
Yes - There is a plan to make this available

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

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

Clinical Study Report
Yes - There is a plan to make this available

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

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

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments