Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 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

Country

Iran (Islamic Republic of)

Phone

+98 31 5522 1286

Email address

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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
Age
From **20 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target 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.
City
Tehran
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 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

Street address
Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, Tehran, Iran
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Postal code
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahin Akhondzadeh
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No. 44, Hojjatdoust St Ave., Naderi st., Keshavarz Blvd.,Tehran
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Province
Tehran
Postal code
0
Phone
+98 21 8895 5742
Email
S.akhond@neda.net
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
Street address
Shariati hospital, Jalal-e-Al-e-Ahmad Hwy, Tehran, Iran
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Phone
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rrc@tums.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Farzaneh Asoudeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position
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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