Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Determining the Effect of Propolis Supplementation on Inflammatory Factors and Oxidative Status in Women with Rheumatoid Arthritis

Protocol summary

Study aim
Determining the Effect of Propolis Supplementation on Inflammatory Factors and Oxidative Status in Women with Rheumatoid Arthritis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 48 patients. The rand function of the Excel software was used for randomization.

Settings and conduct
This study will be held at Emam Reza Hospital. The sample size is 48 and subjects will be distributed in each of 2 groups randomly. Participants and investigators are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People in the age range of 20-70 years; Patients with moderate and severe disease activity score 28; Do not take antioxidant supplements for at least 1 month before starting the study; The tendency to cooperate and sign informed written consent; Diagnosis of the disease by a rheumatologist based on the criteria of the american college of rheumatology Exclusion criteria: Pregnancy and lactation; Taking oral contraceptive pills; History of chronic diseases such as diabetes mellitus, kidney failure, liver failure and cancer; Having other autoimmune and inflammatory diseases; Having hormonal disorders, Thyroid disorders; Alcohol consumption and hookah; Use smoking and being exposed to secondhand smoke

Intervention groups
In this study participants will distribute in 2 groups and each group has 24 individuals. Intervention group: Supplement propolis. Placebo group: Intake of placebo supplement.

Main outcome variables
Assessing the total antioxidant capacity level; Total oxidative status; Alpha tumor necrosis factor; Interleukin 17; Malondialdehyde; Glutathione peroxidase; Superoxide dismutase

General information

Reason for update
The start date of the intervention was postponed due to lack of supplements.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190407043194N2**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **prospective**

Last update: **2022-06-03, 1401/03/13**
Update count: **2**

Registration date
2020-07-22, 1399/05/01

Registrant information

Name
Maryam khosravi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3800 2103

Email address
khosravim@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-06, 1400/05/15

Expected recruitment end date
2022-03-06, 1400/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the Effect of Propolis Supplementation on Inflammatory Factors and Oxidative Status in Women with Rheumatoid Arthritis

Public title
Evaluation the effect of propolis on rheumatoid arthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
People in the age range of 20-70 years Patients with moderate and severe disease activity score 28 Do not take antioxidant supplements for at least 1 month before starting the study The tendency to cooperate and sign informed written consent Diagnosis of the disease by a rheumatologist based on the criteria of the American College of Rheumatology

Exclusion criteria:
Pregnancy and lactation Taking oral contraceptive pills History of chronic diseases such as diabetes mellitus, kidney failure, liver failure and cancer Having other autoimmune and inflammatory diseases Having Hormonal disorders, thyroid disorders Alcohol consumption and hookah smoke Smoking and being exposed to secondhand smoke

Age
From **20 years** old to **70 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will allocate in each group by: Allocation will randomize in blocks of size 4 (two placebos,two propolis) will design by RAS software. Each block will stratify by patient's baseline characteristics of body mass index (less or more than 30 kg/m^2), Severity of disease (moderate or sever) and menstrual status (yes or no).

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study investigator and participants are blind from groups and how they are randomized

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Nutrition Department, Medicine School, Mashhad University of Medical Sciences, University campus, Azadi Square

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2020-07-05, 1399/04/15

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.145

Health conditions studied

1

Description of health condition studied
Arthritis rheumatoid

ICD-10 code
M06.9

ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Total antioxidant capacity

Timepoint
Before and after of intervention

Method of measurement
Elisa kit

2

Description
Interleukin 17

Timepoint
Before and after of intervention

Method of measurement
Elisa kit

3

Description
Total oxidant status

Timepoint
Before and after of intervention

Method of measurement
Elisa kit

4

Description
Tumor necrosis factor alpha
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

5

Description
Malondialdehyde
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

6

Description
Glutathione peroxidase
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

7

Description
Catalase
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

8

Description
Superoxide dismutase
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

9

Description
Triglyceride
Timepoint
Before and after of intervention
Method of measurement
Laboratory test

10

Description
Low density lipoprotein
Timepoint
Before and after of intervention
Method of measurement
Laboratory test

11

Description
High density lipoprotein
Timepoint
Before and after of intervention
Method of measurement
Laboratory test

12

Description
Blood pressure
Timepoint
Before and after of intervention
Method of measurement
Mercury barometer

13

Description
Dietary intake
Timepoint
Before and after of intervention
Method of measurement
Three days food record

14

Description
Physical activity
Timepoint
Before and after of intervention
Method of measurement
International Physical Activity Questionnaire

15

Description
Anthropometric measurements
Timepoint
Before and after of intervention
Method of measurement
Body mass index, waist circumference, Hip circumference

16

Description
High sensivity C-reactive protein
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

17

Description
Monocyte Chemoattractant Protein-1
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

18

Description
Nitric oxide
Timepoint
Before and after of intervention
Method of measurement
Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Propolis supplement (Propolis supplement capsule containing 500 mg of propolis, Shahdineh Golha Pharmaceutical Company, 2 times a day, daily consumption for 3 months, with water).
Category
Prevention

2

Description
Control group: Placebo (placebo capsule containing 500 mg of wheat starch, Shahdineh Golha Pharmaceutical Company, 2 times a day, daily consumption for 3 months, with water).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Maryam Khosravi
Street address
Imam Reza Hospital, Chamran Ave, Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2367
Email
KhosraviM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Saeid Eslami
Street address
Mashhad University of Medical Sciences, University campus, Azadi Square
City
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9177948564
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Email
Eslamis@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
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
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Khosravi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Nutrition Department, medicine School, Mashhad University of Medical Sciences, Univesity campus, Azadi Square
City
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Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2367
Email

Khosravim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Khosravi

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Maryam Khosravi

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Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

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

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Primary outcomes will be share.

When the data will become available and for how long
Starting 6 month after publication

To whom data/document is available
Researchers

Under which criteria data/document could be used
For Metanalysis

From where data/document is obtainable
Making contact with Dr. Mariam Khosravi

What processes are involved for a request to access data/document
Making contact with Dr. Mariam Khosravi and asking for the data, if she approved, request will be send to university president, if they approved the data will send for applicant.

Comments