

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of garlic tablet on inflammatory biomarkers, serum total antioxidant capacity, serum malondialdehyde, fatigue, and clinical symptoms in patients with rheumatoid arthritis.

Protocol summary

Study aim

The effects of garlic tablet on inflammatory biomarkers, serum total antioxidant capacity, serum malondialdehyde, fatigue, and clinical symptoms in patients with rheumatoid arthritis

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment.

Settings and conduct

This double-blind randomized clinical trial will conduct on 70 eligible RA patients. Blocked randomization will run through Random Allocation Software (RAS) to assign patients into two parallel groups (1:1) with four participants in each block. Patients in the intervention group will receive 500 mg garlic tablets twice a day and control group will receive placebo for 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of rheumatoid arthritis by a physician based on criteria (ACR) Having active disease Intake of stable doses of corticosteroids during the past month not inclusion criteria suffering from diabetes mellitus, thyroid disorders, or kidney or hepatic diseases allergy to garlic using warfarin or other anticoagulants

Intervention groups

Patients in the intervention group will receive 500 mg garlic tablets twice a day and control group will receive placebo.

Main outcome variables

The effects of garlic tablet on inflammatory biomarkers, serum total antioxidant capacity, serum malondialdehyde, fatigue, and clinical symptoms in patients with rheumatoid arthritis is assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141108019853N6**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

Registration date

2019-10-01, 1398/07/09

Registrant information

Name

Zamzam Paknahad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3792 3166

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of garlic tablet on inflammatory biomarkers, serum total antioxidant capacity, serum

malondialdehyde, fatigue, and clinical symptoms in patients with rheumatoid arthritis.	
Public title	The effects of garlic tablet in patients with rheumatoid arthritis.
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Diagnosis of rheumatoid arthritis by a physician based on criteria (ACR) Having active disease Intake of stable doses of corticosteroids during the past month.
Exclusion criteria:	
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor
Sample size	Target sample size: 70
Randomization (investigator's opinion)	Randomized
Randomization description	Blocked randomization will run through Random Allocation Software (RAS) to assign patients into two parallel groups (1:1) with four participants in each block.
Blinding (investigator's opinion)	Double blinded
Blinding description	none of the patients, as well as the researcher, clinical care, the outcome evaluator and data analyzer will be aware of the group in which the patients are allocated and the type of intervention received.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Isfahan University of Medical Sciences
Street address	Hezar Jarib Street- Isfahan University of Medical Sciences

City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2019-04-27, 1398/02/07
Ethics committee reference number	IR.MUI.MED.REC.1398.027
Health conditions studied	
<u>1</u>	
Description of health condition studied	rheumatoid arthritis
ICD-10 code	M05
ICD-10 code description	Rheumatoid arthritis disease
Primary outcomes	
<u>1</u>	
Description	Mean difference of serum CRP.
Timepoint	Before and after intervention
Method of measurement	Serum level.
<u>2</u>	
Description	Mean difference of serum TNFa .
Timepoint	Before and after intervention
Method of measurement	Serum level.
<u>3</u>	
Description	Mean difference of serum TAC.
Timepoint	Before and after intervention
Method of measurement	Serum level
<u>4</u>	
Description	Mean difference of serum MDA .
Timepoint	Before and after intervention
Method of measurement	Serum level

5

Description

Mean difference of ESR.

Timepoint

Before and after intervention

Method of measurement

Photo-metric

6

Description

Mean difference fatigue score in fatigue questionnaire

Timepoint

Before and after intervention

Method of measurement

Fatigue questionnaire

7

Description

Mean difference of clinical symptoms.

Timepoint

Before and after intervention

Method of measurement

DAS-28 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group receive 500 mg garlic tablets twice a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: control group receive placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic in shiraz

Full name of responsible person

دکتر زهرا حبیب آگهی

Street address

Namāzī, Karim Khan Zand Blvd

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Shiraz

Province

Fars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr. Shaghayegh Haghjoo Javanmard

Street address

Deputy of Research & Technology of Isfahan

University of Medical Sciences-Hezar Jarib

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Zamzam Paknahd

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available