

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of chamomile (*Matricaria recutita* L.) on serum levels of tumor necrosis factor- α (TNF- α), interleukin-1 β and matrix metalloproteinase-3 (MMP3) in rheumatoid arthritis women patients: a randomized controlled clinical trial

Protocol summary

Summary

Forty four adult female patients with rheumatoid arthritis (RA), diagnosed in accordance with criteria suggested by 2010 American College of Rheumatology (ACR) criterion, with remission to moderate disease activity score will be recruited in the study. Although patients receiving inconstant drug prescription for 3 weeks before and during the intervention, subjects suffering from inflammatory or metabolic disorders and those with pregnancy or lactation will be excluded. The participants will be assigned into treatment group (22subject) and control group (22subject) using permuted-blocks randomization and will receive two glasses of chamomile and placebo herbal tea for 6 weeks. To determine the effects of chamomile on patient's clinical status, disease activity score (DAS-28) will be calculated before and after the intervention for each group. Inflammatory biomarkers such as interleukin-1 β , TNF- α (tumor necrosis factor- α) and MMP-3 (matrix metalloproteinase 3) will be measured with ELISA method in serum samples collected before and after the study (6weeks). Finally, to manage effects of any confounder variable, anthropometric indicators, physical activity level and mental anxiety status will be measured and a three-day food record will be kept in two period, in onset and end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010111335N4**

Registration date: **2015-01-28, 1393/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-28, 1393/11/08

Registrant information

Name

Saeed Pirouzpanah

Name of organization / entity

Nutrition Faculty, Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of chamomile (*Matricaria recutita* L.) on serum levels of tumor necrosis factor- α (TNF- α), interleukin-1 β and matrix metalloproteinase-3 (MMP3) in rheumatoid arthritis women patients: a randomized controlled clinical trial

Public title

The effect of chamomile (*Matricaria recutita* L.) on serum levels of tumor necrosis factor- α (TNF- α), interleukin-1 β and matrix metalloproteinase-3 (MMP3) in rheumatoid arthritis women patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Subjects diagnosed with rheumatoid arthritis, based on American College of Rheumatology (ACR-2010) criteria; 2) Patients with moderate and less rheumatoid arthritis score (DAS-28<5.1); 3) Stable medication for at least 3 weeks prior to the intervention and during that; 4) Willing to participate in the study and giving written consent ; 5) Ages between 20 and 65; 6) Have a body mass index (BMI) less than 30 and more than 18.5 Exclusion criteria: 1) Pregnant and lactating women; 2) Patients with cardiovascular, lung, hepatic, kidney and blood diseases; 3) Having chronic inflammatory diseases such as Sjogern, Sicca, Multiple sclerosis, Lupus Erythematosus and Hashimoto's diseases; 4) Patients with gastroduodenal ulcer; 5) Patients with a high sensibility to the experimental drugs; 6) Patients participating in another study just 3 weeks before the intervention; 7) Taking any vitamin, mineral or omega 3 supplement 3 months before the intervention.

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Regard to compliance criterion, subjects will receive similar packets and teabags (shape, size, color were similar) containing chamomile and placebo. For being sure that diet pattern had no change during the study, patients were asked to fill 3 days 24-hours food record before and after the intervention. Patients were requested to continue to their usual life style and diet pattern during run-out period. Although physical activity and drug usage will be questioned in 3 weeks intervals and at the end of study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Tabriz University of Medical Science

Street address

Golbad Street, Tabriz, Eastern Azarbaijan, Islamic Republic Of Iran

City

Tabriz

Postal code

Iran

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

5442/4/5

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

Intelukin 1- β (IL-1 β), Tumor Necrosis Factor-alpha(TNF-alpha)

Timepoint

At baseline and after 6 weeks of intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Matrix metalloproteinase 3 (MMP-3)

Timepoint

At baseline and after 6 weeks of intervention

Method of measurement

ELISA

Intervention groups

1

Description

The case group will receive two glasses of chamomile tea, containing 3 grams chamomile (plus 3 grams bran)

brewed in 150 ml of water every day for six consecutive weeks. Chamomile flowers will be dried with a standard method and away from the light and in an instant time interval. Plant species will be confirmed by herbarium. Tea packing will be done in the tea company. All the patients will receive the supplements on the onset of the study and will be monitored for consumption continuation and any possible adverse effects by telephone calls. In addition consumption check lists were collected every 3 weeks during the study. Before the intervention of study, a run out period was planned for flavonoid rich foods such as black tea (less than 2 cups with 240ml volume), onion, and green leafy vegetables seven days before the intervention and during the study. Investigator and patients were blinded about grouping the participants into placebo or intervention group. Tea bags were distributed to participants with similar packing which was coded by producer factory. Subjects were requested to follow their usual diet and physical activity plan of their life.

Category

Treatment - Other

2

Description

The control group as placebo will receive two tea bags containing 3 grams of wheat bran as placebo every day for six consecutive weeks. The placebo packing will be done in the tea company. All the patients will receive the placebos on the onset of the study and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Atiye Specialized Rheumatology Center

Full name of responsible person

Mehrzad Hajaliloo

Street address

Atiye building, Golgasht tee, Azadi Street, Tabriz, Eastern-Azarbaijan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Bahram Pourghasem

Street address

Golbad Street, Tabriz, Eastern-Azarbaijan, Islamic Republic of Iran

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

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Saeed Pirouzpanah

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Soltan-Ali Mahboob and Dr. Saeed Pirouzpanah

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Professor (S.A.M.), Assistant Professor (S.P.)

Other areas of specialty/work

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Full name of responsible person

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Position

Nutrition (Candidate of M.Sc. degree)

Other areas of specialty/work

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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