Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of chamomile (Matricaria recutita L.) on serum levels of tumor necrosis factor-α (TNF-α), interlukin-1β 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 interlukin-1β, 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

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Saeed Pirouzpanah
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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), interlukin-1β 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), interlukin-1β 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-1ß), 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

City

Tabriz

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

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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