

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effects of brewed tea of poulk (*Stachys Schtschegleevii*) on some biochemical parameters and disease activity in women with rheumatoid arthritis: a randomized controlled clinical trial

Protocol summary

Summary

The present study is a randomized double-blinded placebo-controlled clinical trial aimed to investigate the effects of brewed tea of poulk (*Stachys Schtschegleevii*) on some biochemical parameters and disease activity in women with rheumatoid arthritis. Patients will be recruited from the rheumatology clinics of Tabriz University of Medical Sciences, Tabriz, Iran. After giving written informed consent, 42 female RA patients who met the inclusion criteria will be included in the study. Then, they will be randomly assigned 1:1 to two groups to receive either the main intervention (2.4 gram of poulk with 2.4 gram of black tea) or placebo (2.4 gram of black tea) for 8 weeks (2 times a day, after lunch and dinner, each time the dried herbal powder in 240 ml boiled water, with brewing time of 20 minutes). At the beginning of the study demographic data (including age, disease history, educational status, etc) will be collected. Anthropometric parameters (height, weight, body mass index, waist and hip circumferences), disease activity (based on disease activity score in 28 joints) and serum biomarkers (interleukin-1, tumor necrosis factor-alpha, high sensitive-c reactive protein, matrix metalloproteinase-1 and matrix metalloproteinase-3) will be evaluated at baseline and after 8 weeks. Moreover, at initial and final points, physical activity level and dietary intake are assessed using the international physical activity questionnaire and a three-day dietary record respectively. Finally, biochemical, clinical, anthropometric and dietary data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015032011335N5**
Registration date: **2015-05-12, 1394/02/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-12, 1394/02/22

Registrant information

Name

Saeed Pirouzpanah

Name of organization / entity

Nutrition Faculty, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41133575803

Email address

pirouzpanahs@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Connective Tissue Diseases Research Center

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of brewed tea of poulk (*Stachys Schtschegleevii*) on some biochemical parameters and disease activity in

women with rheumatoid arthritis: a randomized controlled clinical trial

Public title

Effects of brewed tea of poulk in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Subjects diagnosed with rheumatoid arthritis based on American College of Rheumatology and European League Against Rheumatism (ACR-EULAR) 2010 criteria for RA; Desire to attend in the study and signing the informed consent form; Desire to fill in the questionnaires and participate in sampling; Age range of 30 to 65 years; Being diagnosed with active rheumatoid arthritis (disease activity score-28 more than 3.2); Not receiving antioxidant or anti-inflammatory supplements since one month prior to the study Exclusion criteria: Pregnancy; Lactation; Presence or history of other kinds of diseases and cancers; Other acute or chronic inflammatory diseases (such as colitis, psoriasis); AIDS; Sepsis; Type 2 diabetes mellitus; Thyroid disorders; Having side effects with poulk consumption besides drug side effects; Severe obesity (body mass index more than 40); Taking antioxidant supplements during the study; Smoking or being a passive smoker; Changing diet, physical activity and lifestyle during the study period; Unwillingness to continue the study

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical

Sciences

Street address

Golgasht Street, Tabriz, Eastern Azarbaijan, Iran

City

Tabriz

Postal code**Approval date**

2015-02-09, 1393/11/20

Ethics committee reference number

93169

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**

Clinical Outcomes (disease activity score in 28 joints)

Timepoint

Before and after the 8-week intervention

Method of measurement

Using validated questionnaire

2**Description**

Serum levels of inflammatory factors (intelukin-1, tumor necrosis factor-alpha, high sensitive-c reactive protein)

Timepoint

Before and after the 8-week intervention

Method of measurement

Using commercially available kits and ELISA method

3**Description**

Serum levels of matrix metalloproteinases: matrix metalloproteinase-1 and matrix metalloproteinase-3

Timepoint

Before and after the 8-week intervention

Method of measurement

Using commercially available kits and ELISA method

Secondary outcomes**1****Description**

Dietary intake of energy and nutrients

Timepoint

Before and after the 8-week intervention

Method of measurement

Using 3-day dietary record

2

Description

Anthropometric parameters (height, weight, body mass index, waist and hip circumferences)

Timepoint

Before and after the 8-week intervention

Method of measurement

Body weight is measured using a calibrated scale (Seca, Germany) to the nearest 0.5 kilogram. Standing height without shoes and circumferences of waist and hip are measured using a non-stretchable tape (Seca) to the nearest 0.5 centimeters. Body mass index is calculated through dividing weight (kilogram) by the height squared (meters).

Intervention groups

1

Description

Intervention group: brewed tea of poulk (daily consumption of 2.4 gram dried powder of poulk with 2.4 gram dried powder of black tea), for 8 weeks (2 times a day, after lunch and dinner, each time dried powder of herbal composition in 240 ml boiled water, with brewing time of 20 minutes)

Category

Treatment - Other

2

Description

Control group: brewed black tea (daily consumption of 2.4 gram dried powder of black tea, for 8 weeks (2 times a day, after lunch and dinner, each time the dried powder of black tea in 240 ml boiled water, with brewing time of 20 minutes)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Atieh Clinic

Full name of responsible person

Dr. Alireza Khabbazi

Street address

Atieh Clinic, Azadi Street, Tabriz, Eastern Azerbaijan, Iran

City

Tabriz

2

Recruitment center

Name of recruitment center

Golgasht Clinic

Full name of responsible person

Dr. Susan Kolahi

Street address

Golgasht Clinic, Azadi Street, Tabriz, Eastern Azerbaijan, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Connective Tissue Diseases Research Center

Full name of responsible person

Dr. Alireza Khabbazi

Street address

Connective Tissue Diseases Research Center, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht street, Tabriz, Eastern Azerbaijan, Iran

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Connective Tissue Diseases Research Center

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

Ph.D. of Nutrition, Assistant Professor

Other areas of specialty/work

Street address

Attar Neyshaboori Street, Golgasht Street, Tabriz, Eastern-Azerbaijan, Iran.

City

Tabriz

Postal code

Phone

+98 41 3335 7581

Fax
+98 41 3336 8805
Email
pirouzpanahs@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Nutrition, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Saeed Pirouzpanah
Position
Ph.D. of Nutrition, Assistant Professor
Other areas of specialty/work
Street address
Attar Neyshaboori Street, Golgasht Street, Tabriz, Eastern-Azerbaijan, Iran
City
Tabriz
Postal code
Phone
+98 41 3335 7581
Fax
+98 41 3336 8805
Email
pirouzpanahs@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

Elham Mirtaheri

Position

M.Sc. of Nutrition

Other areas of specialty/work

Street address

Attar Neyshaboori Street, Golgasht Street, Tabriz, Eastern-Azerbaijan, Iran

City

Tabriz

Postal code

Phone

+98 41 3335 7581

Fax

+98 41 3336 8805

Email

e.mirtaheri@yahoo.com

Web page address

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