Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (intelukin-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

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