Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study the Effect of a Fig and Olive Oil Preparation on Remission Indicators of Rheumatoid Arthritis (RA) based on the Iranian Traditional Medicine and the Modern Medicine

Protocol summary

Summary

This study is a randomized clinical trial in which effect of a combination of olive oil and fig on the remission of the signs and symptoms of patients with RA referred to the outpatient clinic of a teaching hospital (The Loghman Hakim hospital) will be investigated. Patients will be divided into two groups consisting of 29 patients in each group. The first group (control group) will continue the standard treatment of RA i.e. DMARDS and adjunctive agents, while the second group (treatment group) will receive the herbal study preparation (olive oil plus powdered fig suspension) along with the standard therapy of RA. Clinical outcomes and laboratory findings will be measured and recorded for each patient at the beginning (baseline) and every 4 weeks for 16 weeks. The study outcomes are determined based on the traditional medicine literature as well as those recommended by classical medicine guidelines. Study objective is to determine and compare the remission indicators of RA in two study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122015876N1**
Registration date: **2014-03-03, 1392/12/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-03, 1392/12/12

Registrant information

Name

Shahnaz Bahadori

Name of organization / entity

School of Traditional Medicine

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Faculty of Traditional Medicine, Tehran University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effect of a Fig and Olive Oil Preparation on Remission Indicators of Rheumatoid Arthritis (RA) based on the Iranian Traditional Medicine and the Modern Medicine

Public title

Effect of olive oil and fig on Rheumatoid Arthritis (RA)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male and female patients with active RA who has a DAS-28 of minimum 2.6; age over 18 years old; patients on standard DMARDS therapy and

adjunctive agents; not receiving biologic DMARDS in the past 6 months. Exclusion criteria: patients with concurrent rheumatoid diseases or gout; patients with uncontrolled Diabetes Mellitus; patients with a major change in their ordinary diet; patients receiving other traditional medicine therapies during study period; i. pregnancy; patients with a history of continuous fig and olive oil consumption in the last 3 months; history of inter-articular injection of corticosteroids in the last 3 months as well as during the study period; any kind of addiction or drug abuse; occurrence of severe adverse reactions due to intervention; patient unwillingness to fulfill the study; patient non-compliance on regular use of the study medicine defined as >20% non-adherence in taking the study drug.

Age
From **19 years** old to **100 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is designed as an add-on therapy, so that one group will receive the standard treatment and the other group will take the study drug plus standard treatment

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Faculty of Traditional Medicine, Tehran University of Medical Sciences

City
Tehran

Postal code

Approval date
2014-01-20, 1392/10/30

Ethics committee reference number
92-01-86-21568-103137

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis

ICD-10 code
M05

ICD-10 code description

Primary outcomes

1

Description
DAS28-ESR

Timepoint
at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement
Number of tender joints, Number of swellen joints, ESR values, patient self-assessment of the disease. These data will be entered the specific formula to calculate the DAS28-ESR.

2

Description
Urine color (as a traditional medicine outcome)

Timepoint
at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement
qualitative observation of the urine color using traditional medicine criteria

3

Description
Urine viscosity

Timepoint
at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement
observation of the urine based on the traditional medicine criteria

4

Description
Joints Pain

Timepoint
at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement
number of paifull joints and its severity using VAS scale

Secondary outcomes

1

Description

FBS

Timepoint

at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement

lab test

2

Description

lipid profile

Timepoint

at the begining of study (baseline) and every 4 weeks for 16 weeks

Method of measurement

lab test

3

Description

change in the use of NSAIDs (dose or frequency)

Timepoint

during 16 weeks of study

Method of measurement

self-report and doctor's order

4

Description

change in the use of corticosteroids

Timepoint

during 16 weeks ofstudy period

Method of measurement

self-report and doctor's order

5

Description

possible adverse reaction of diarrhea

Timepoint

monitoring over the study period

Method of measurement

self-report and medical history of patient taken every 4 weeks

Intervention groups

1

Description

15 ml of the study preparation (olive oil and fig as oral suspension), bd, 16 weeks; along with standards treatment (DMARDs)

Category

Treatment - Drugs

2

Description

Control: standard treatment of RA (DMARDs)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Loghman Hakim Teaching Hospital

Full name of responsible person

Shahnaz Bahadori

Street address

Faculty of Traditional Medicine, Tehran Uni. Med. Sci.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Masoud Younesian

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Tehran University of Medical Sciences, Qods st., Kshavarz blvd.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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 traditional Medicine, Tehran Uni. Med. Sci.

Full name of responsible person

Dr Mohammad Reza Shams Ardekani

Position

PhD of Pharmacognosy, Professor

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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