

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

A clinical trial of comparing the effect of sea buckthorn extract with placebo on clinical symptoms of patients with rheumatoid arthritis

Protocol summary

Study aim

Evaluation of the effect of sea buckthorn extract in patients with rheumatoid arthritis

Design

Clinical trial, with control and intervention group, Triple blinded, random number table using www.randomization.com (n=11)

Settings and conduct

Divide patients into two groups by random number table: A and B Group Intervention group will receive standard treatment with 500 mg sea buckthorn capsule and the placebo group, standard treatment with placebo capsule. Method of producing the capsule: 1- Making the hydro alcoholic extract (70%) of the aerial parts of the plant by soaking method. 2- Formulation of the extract as a capsule Duration of treatment: 12 weeks Place of study: Laboratory of the School of Persian and Complementary Medicine, Ghaem Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 50 years, recent diagnosis according to ACR/EULAR criteria, not receiving any previous treatment for rheumatoid arthritis, disease severity between 5.2 to 5.5 according to DAS criteria Exclusion criteria: history of MI, hyperlipidemia, impaired hepatic or renal function, malignancies and psychiatric illness or active infection, use of vitamin/mineral supplements or medications such as thyroid hormones, anti-HTN drugs, contraceptives, Diuretics, beta-blockers, alcohol and smoking, allergy to sea buckthorn, as well as pregnancy and lactation, disease severity above 5.5 according to DAS criteria, injection of any intra-articular drug during the study period

Intervention groups

Intervention group: receiving the main treatment with sea buckthorn capsule Control group: receiving the main treatment with placebo capsules

Main outcome variables

Measurement of demographic indicators Disease activity by DAS28-ESR, HAQ-DI, VAS and PS questionnaires

Evaluation of laboratory data (whole blood test, ESR, ANA, Cr, Urea, LFT, BUN) at the beginning and end of the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210630051742N1**

Registration date: **2021-11-13, 1400/08/22**

Registration timing: **prospective**

Last update: **2021-11-13, 1400/08/22**

Update count: **0**

Registration date

2021-11-13, 1400/08/22

Registrant information

Name

MohammadAli Emrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 8931

Email address

m.emrani1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A clinical trial of comparing the effect of sea buckthorn extract with placebo on clinical symptoms of patients with rheumatoid arthritis

Public title
The effect of sea buckthorn on clinical symptoms of rheumatoid arthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed patient based on ACR/EULAR criteria for rheumatoid arthritis. Patient who has received no medication for rheumatoid arthritis until now. Disease severity should be between 2.5 to 5.5 based on DAS criteria.
Exclusion criteria:
Patient MI history Patient has hyperlipidemia Patient has liver or kidney impaired function. Patient has any neoplasm Patient has psychiatric diseases. There is active infection in patient's body. Patient takes vitamin/mineral supplements. Patient takes medications like thyroid hormones, Anti hypertensives, contraceptives, diuretics and beta-blockers. Patient drinks alcohol or smokes. Patient has any allergy to sea buckthorn. Patient is pregnant or breastfeeds. Disease severity is above 5.5 based on DAS criteria.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyster

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: A simple randomization method that uses a table of random numbers or computer methods to place people in the control or intervention group. Unit of randomization: Individual
Tools used in randomization: Table of random numbers by using of randomization.com. allocation concealment: Sealed envelopes

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this Triple-blind study, capsules will be similar, and neither patients nor researchers nor analyzers know the type of capsule (Placebo/Sea buckthorn) received.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Khorasan Razavi, Mashhad, Doctora intersection, Ghorashi building
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191

Approval date
2021-06-19, 1400/03/29

Ethics committee reference number
IR.MUMS.REC.1400.063

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M05

ICD-10 code description
Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description
Severity of pain

Timepoint
before intervention and 30, 45, 90 days after intervention

Method of measurement
visual analog scale

2

Description
number of tender joints

Timepoint
before intervention and 30, 45, 90 days after intervention

Method of measurement

3

Description

number of swollen joints

Timepoint

before intervention and 30, 45, 90 days after intervention

Method of measurement

Disease Activity Score Calculator for Rheumatoid Arthritis

4

Description

ESR

Timepoint

Before intervention and 90 days after intervention

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 milligram capsule of sea buckthorn extract, once daily, up to 90 days, manufactured in School of Persian and complementary medicine of Mashhad university of medical sciences

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule, once daily, up to 90 days, manufactured in School of Persian and complementary medicine of Mashhad university of medical sciences

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatic Diseases Research Center

Full name of responsible person

Mohammadali Emrani

Street address

Rheumatology Diseases Research Center, Office Building in Qaem Hospital, 1st floor, Mashhad - Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan

Street address

Mashhad, Vice Chancellor for Research, Mashhad University of Medical Sciences, Doctora intersection, Ghorashi building

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Grant name

Dr. Roshanak Salari

Grant code / Reference number

991859

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Roshanak Salari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Azadi square, university campus, School of Persian and complementary medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr.Roshanak Salari

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available