Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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/EULAER 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)

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+98 51 3884 8931

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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/EULAER 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 analyser

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 envelops

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

Disease Activity Score Calculator for Rheumatoid Arthritis

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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salarir@mums.ac.ir
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
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Person responsible for updating data

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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