

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effects of Hydroalcoholic Extract of Black Barberry Fruit on some immunity mediators in Active Rheumatoid Arthritis Patients

Protocol summary

Summary

This study will examine effects of hydroalcoholic extract of black barberry fruit on some immunity mediators in patients with active RA referring to Shariaty Hospital. In a randomized, double blind, placebo controlled clinical trial, 80 patients, aged between 18-69 years old with active RA after rheumatologist examination and filling personal, medical and food questionnaires will be enrolled in the study. They will be divided in 2 groups (40 numbers in each group) including: 1- Black barberry consumers (case) and 2-Placebo consumers (control) randomly. Patients in case group will receive 2000 mg of hydroalcoholic extract of black barberry daily (by two 1000 mg capsules) for 3 months and control patients will receive 2000 mg maltodextrin daily (by two 1000mg capsules) , one 1000 mg capsule before lunch and one before dinner respectively for 3 months. Placebo capsules are completely similar to the others and will be given randomly to Patients. Patients will be control by calling weekly and visiting monthly. for comparing two groups before and after the 3 months intervention period these tests will be operated on them: IL-2, IL-4, IL-10, IL-17 and BMI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510259472N8**

Registration date: **2016-04-03, 1395/01/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4750

Email address

aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice-chancellor for research, Iran University of Medical Science

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Hydroalcoholic Extract of Black Barberry Fruit on some immunity mediators in Active Rheumatoid Arthritis Patients

Public title

Effects of Hydroalcoholic Extract of Black Barberry Fruit in Active Rheumatoid Arthritis Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: person with RA disease as American College of Rheumatology (ACR) criteria; age between 18-69 years; having RA from 1 years ago; active

rheumatoid arthritis; acceptance of patient; not having diabetes mellitus, hypertension, thyroid problem, renal failure and liver dysfunction; not smoking; not being pregnant or lactated; not receiving omega-3 or antioxidants supplements from 3 month ago; not getting contraceptive drugs; exclusion criteria: reluctance for continuing the cooperation ; taking less than 80% of supplements given to patients at baseline (the compliance lower than %80); sudden stricken to an acute disease; migration ; any change in drug and treatment protocol that can cause omission from study.

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 in research of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad tower, between Sheikh Fazlollah Noori and Chamran highway, Hemmat highway, Tehran, Iran

City

Tehran

Postal code**Approval date**

2016-03-09, 1394/12/19

Ethics committee reference number

IR.IUMS.REC.1394.27.85

Health conditions studied**1****Description of health condition studied**

Active rheumatoid arthritis

ICD-10 code

M06.8

ICD-10 code description

Other specified rheumatoid arthritis

Primary outcomes**1****Description**

IL2

Timepoint

First day and three months later

Method of measurement

Elisa

2**Description**

IL4

Timepoint

First day and three months later

Method of measurement

Elisa

3**Description**

IL10

Timepoint

First day and three months later

Method of measurement

Elisa

4**Description**

IL17

Timepoint

First day and three months later

Method of measurement

Elisa

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

BMI

Timepoint

First day and three months later

Method of measurement

Calculation

Intervention groups

1

Description

Taking Hydroalcoholic extract of black barberry supplement, 2000 miligram (2* 1000 milligrams capsules aqueous extract of black barberry per day for 3 months (12 weeks)

Category

Other

2

Description

Taking placebo, 2000 miligram (2* 1000 milligrams capsules) maltodextrin per day for 3 months (12 weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology research center

Full name of responsible person

Dr. Farhad Shahram

Street address

Shariaty hospital, Jalal Ale Ahmad street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice-chancellor for research, Iran University of Medical Science

Full name of responsible person

Dr Ali Javadmoosavi

Street address

Iran University of Medical Sciences, Hemmat highway, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice-chancellor for research, Iran University of Medical Science

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

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

PhD in nutrition

Other areas of specialty/work

Street address

School of health, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

n-aryaeian@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

PhD in nutrition

Other areas of specialty/work

Street address

School of health, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

n-aryaeian@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

PhD in nutrition

Other areas of specialty/work

Street address

School of health, Iran University of Medical Sciences,
Hemmat highway

City

Tehran

Postal code**Phone**

+98 21 8877 9118

Fax**Email**

n-aryaeian@sina.tums.ac.ir

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