Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of aqueous extract of black barberry fruit on clinical signs, some inflammatory factors, glycemic profile, lipid Profile, blood pressure, and percent of body fat in active rheumatoid arthritis patients

Protocol summary

Summary

This study will examine effects of aqueous extract of black barberry fruit on clinical signs, some inflammatory factors, glycemic profile, lipid profile, blood pressure and percent of body fat 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 aqueous 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: hs-CRP, TNF α, ESR, FBS, TC, TG, LDL, HDL clinical signs, blood pressure, body fat percent, BMI and waist circumference will be assessed too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409249472N7**
Registration date: **2015-01-18, 1393/10/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-01-18, 1393/10/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

vice- chanceller for research, Iran University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of aqueous extract of black barberry fruit on clinical signs, some inflammatory factors, glycemic profile, lipid Profile, blood pressure, and percent of body fat in active rheumatoid arthritis patients

Public title

Effects of aqueous extract of black barberry fruit on

active rheumatoid arthritis Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: person with RA disease as American College of Rheumatology (ACR) criteria; age between 20-69 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 strickening 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 commitee 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

2015-01-05, 1393/10/15

Ethics committee reference number

25092-93/10/15

Health conditions studied

1

Description of health condition studied

Active rheumathoid arthritis

ICD-10 code

M06.8

ICD-10 code description

Other specified rheumatoid arthritis

Primary outcomes

1

Description

pain

Timepoint

First day and three months later

Method of measurement

visual analogue scales

2

Description

Morning stiffness

Timepoint

First day and three months later

Method of measurement

Examintion

3

Description

Number of inflammated joints

Timepoint

First day and three months later

Method of measurement

Examintion

4

Description

DAS28

Timepoint

First day and three months later

Method of measurement

Examintion

5

Description

hs-CRP

Timepoint

First day and three months later

Method of measurement

elisa

6

Description
TNF α
Timepoint
First day and three months later
Method of measurement
Elisa

7

Description
ESR
Timepoint
First day and three months later
Method of measurement
Westergren

8

Description
FBS
Timepoint
First day and three months later
Method of measurement
GOD/POD

9

Description
TC
Timepoint
First day and three months later
Method of measurement
Enzymatic

10

Description
TG
Timepoint
First day and three months later
Method of measurement
Enzymatic

11

Description
LDL
Timepoint
First day and three months later
Method of measurement
Formula

12

Description
HDL
Timepoint
First day and three months later
Method of measurement
Enzymatic

13

Description
Systolic and diastolic blood pressure
Timepoint
First day and three months later
Method of measurement
Mercuyi barometer

14

Description
Body fat percent
Timepoint
First day and three months later
Method of measurement
BIA

Secondary outcomes

1

Description
Body mass index
Timepoint
First day and three months later
Method of measurement
Calculation

Intervention groups

1

Description
Taking aqueous 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
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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*