Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 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
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

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Person responsible for updating data

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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