Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effect of purslane supplementation on clinical outcomes, inflammatory and oxidative stress markers in patients with rheumatoid arthritis: A parallel double-blinded randomized controlled clinical trial

Protocol summary

Study aim
Assessing the effect of purslane supplementation on clinical outcomes, inflammatory and oxidative stress markers in patients with rheumatoid arthritis

Design
Clinical trial with control group, double-blind, randomized, phase 2 on 86 patients.

Settings and conduct
Rheumatoid arthritis patients referred to shariati Hospital in Tehran who are eligible for the study will have a blood test once at the beginning and once after the intervention and the factors will be measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of Rheumatoid Arthritis Based on American College of Rheumatology (ACR) Criteria(If there are at least four criteria for six weeks of the criteria 1- Morning dryness for at least one hour in three joints or more 2- Arthritis of three joint areas or more 3- Arthritis of the hand joints 4- Symmetric arthritis 5- Rheumatoid nodules 6- Positive rheumatoid factor 7- Typical radiographic changes in the wrist and hand);The duration of the disease is at least one year;The patient expresses his / her consent to participate in the study Criteria for non-inclusion: Having any of the diseases of diabetes, hypertension, thyroid disorder and kidney failure and Liver dysfunction;Smoking;Taking supplements (omega 3, antioxidants, etc.) in the last three months;Taking contraceptives;Changes in the amount of medication taken in the past month;pregnancy and lactation

Intervention groups
Two groups of 43 people with rheumatoid arthritis:43 people in the group receiving 500 mg purslane capsule and 43 people in the placebo receiving group (Maltodextrin capsule)

Main outcome variables
Hs-CRP; TNF-α; SOD; TAC; ESR;GPA; Number of painful joints; Number of inflamed joints; the pain;DAS28; joint stiffness;Telopeptide C;OC;PTH;ALP;CA

General information

Reason for update
Hello and respect The data added to the study, with the aim of conducting a secondary clinical study entitled the effect of purslane extract on some bone markers in patients with rheumatoid arthritis: a parallel double-blind randomized clinical trial approved by the code of ethics IR.IUMS.REC.1403.312, from The main plan is done.

Acronym

IRCT registration information
IRCT registration number: **IRCT20120415009472N25**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2024-08-06, 1403/05/16**
Update count: **1**

Registration date
2022-06-21, 1401/03/31

Registrant information

Name
Naheed Aryaeian
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01
Expected recruitment end date
2023-02-20, 1401/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of purslane supplementation on clinical outcomes, inflammatory and oxidative stress markers in patients with rheumatoid arthritis: A parallel double-blinded randomized controlled clinical trial

Public title
Effect of purslane on the control of rheumatoid arthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of Rheumatoid Arthritis Based on American College of Rheumatology (ACR) Criteria(If there are at least four criteria for six weeks of the criteria 1- Morning dryness for at least one hour in three joints or more 2- Arthritis of three joint areas or more 3- Arthritis of the hand joints 4- Symmetric arthritis 5- Rheumatoid nodules 6- Positive rheumatoid factor 7- Typical radiographic changes in the wrist and hand) The duration of the disease is at least one year The patient expresses his / her consent to participate in the study
Exclusion criteria:
Having any of the diseases of diabetes, hypertension, thyroid disorder and kidney failure and Liver dysfunction Smoking Taking supplements (omega 3, antioxidants, etc.) in the last three months Taking contraceptives Changes in the amount of medication taken in the past month Patients who have followed a specific diet in the last three months Pregnancy and lactation
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of assigning letters A and B on medicine and placebo: The pharmacist uses the coin toss and his personal contract to select the letter A or B for the drug and the other letter will be assigned to the pharmacist. And will stick these letters on the packages. From the type of drug label and placebo until the end of data analysis, the researcher, patient and analyst will not know and this position will remain confidential. Method of assigning letters A and B to patients randomly: Patients who refer to shariati Hospital for treatment of rheumatoid arthritis and are eligible for the study are based on a randomized list, which randomly divides the numbers 1 to 86 using SPSS software in letters A and B (each 43 items) will receive a medicine or placebo with the appropriate label.
Blinding (investigator's opinion)
Double blinded
Blinding description
purslane or placebo is coded by a third person who does not know the contents of the packages. Upon each person entering the study, based on the generated sequence, a packages containing the powder in which the code is recorded will be assigned to the person. None of the participants as well as the researcher and analyst will know the assigned groups. The packages are prepared by the company and placebo and purslane packages are similar in terms of internal and external appearance. After analyzing the data, the pharmacist will be asked for the title of the label (drug or placebo) to compile the report and write the findings section.
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
Province
Tehran
Postal code
1449614535
Approval date
2022-04-26, 1401/02/06
Ethics committee reference number
IR.IUMS.REC.1401.052

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M05.9
ICD-10 code description
Rheumatoid arthritis with rheumatoid factor, unspecified

Primary outcomes

1

Description
High-Sensitivity C-Reactive Protein (hs-CRP)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

2

Description
Tumour necrosis factor- α(TNF-α)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

3

Description
Total antioxidant capacity (TAC)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Chromatography

4

Description
Erythrocyte sedimentation rate(ESR)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Vacuum tube erythrocyte sedimentation rate

5

Description
Superoxide dismutase(SOD)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Spectrophotometry

6

Description
Tender joint counts (TJC)
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Doctor checkup

7

Description
Swollen joint count
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Doctor checkup

8

Description
Illness severity
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Physician global assessment

9

Description
Pain
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Visual analogue scale

10

Description
Disease activity score
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
Formula DAS28

11

Description
Morning stiffness
Timepoint
Before the intervention and after the end of the intervention
Method of measurement
How long (minutes) it takes for the joint dryness to go away.

12

Description

Number of painful joints

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Doctor checkup

13

Description

Telopeptide C

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

14

Description

Osteocalcin

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

15

Description

Parathyroid hormone(PTH)

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

16

Description

Serum alkaline phosphatase(ALP)

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

17

Description

Serum calcium

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Chromatography

Secondary outcomes

1

Description

Dosage of non-steroidal anti-inflammatory drugs

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Questionnaire

2

Description

BMI

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Formula

3

Description

Waist

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Tape meter

4

Description

Blood pressure

Timepoint

Before the intervention and after the end of the intervention

Method of measurement

Manometer

Intervention groups

1

Description

Intervention group: 43 people in the group receiving 500 mg capsules of portulaca oleracea extract from Perpin Ala-Exir Jahani Company (two per day, one after breakfast and one after dinner)

Category

Treatment - Drugs

2

Description

Control group: 43 people in the group receiving maltodextrin placebo capsules (capsules made exactly the same in appearance, color, smell, taste and without therapeutic effect by Perpin Alla-Elixir Global) two per day, one after breakfast and one after From dinner

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital

Full name of responsible person
Masoomeh Akhlaghi Kolahroodi

Street address
North Kargar St., Jalal Al-Ahmad Three-Way, Shariati Hospital

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Reza Falak

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Hemmat highway

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Naheed Aryaeian

Position
Associate Professor of Nutritional Sciences, Iran University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Nutrition department, school of public health, Hemmat broad way

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Person responsible for scientific inquiries

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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only a section of the data, such as primary outcomes information or the like, will be shared

When the data will become available and for how long
Access period start 5 months after results publishing.

To whom data/document is available
The obtained data from current study will be available only for working researchers in academic and scientific institutions

Under which criteria data/document could be used
5 months after the publicized papers from this study, the obtained data will be available to the researchers for further analysis.

From where data/document is obtainable
Applicants can be communicated to correspond author be e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of Public Health, Iran University of Medical Sciences, Hemat Highway, Tehran Cell phone: +982186704743 Email: n-aryaeian@sina.tums.ac.ir

What processes are involved for a request to access data/document
Publishing in scientific-research journals Applicants will be given access to the obtained data from current study by sending an email to correspond author.

Comments