

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Saffron supplement on clinical outcomes, inflammatory and oxidative markers in patients with active rheumatoid arthritis

Protocol summary

Summary

This study will examine the effect of Saffron supplement on clinical outcomes, inflammatory and oxidative markers in patients with active rheumatoid arthritis referring to Hazrat Rasoul Akram Hospital. In a randomized, double blind (both patients and investigator), placebo controlled clinical trial, 66 patients, aged over 18 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 (33 numbers in each group) including: 1- saffron powder consumers (case) and 2-Placebo consumers (control) randomly. Patients in case group will receive Saffron pill containing 100 mg Saffron powder once a day for 12 weeks and control patients will receive Placebo pill containing 100 mg " maltodextrin " once a day for 12 weeks. 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 the intervention and 12 weeks after intervention clinical outcomes will be assessed and these tests will be operated on them: ESR, hs-CRP, MDA, TAC, TNF- α , IFN- γ .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707139472N14**

Registration date: **2017-09-15, 1396/06/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

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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 Sciences

Expected recruitment start date

2017-10-21, 1396/07/29

Expected recruitment end date

2018-10-21, 1397/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Saffron supplement on clinical outcomes, inflammatory and oxidative markers in patients with active rheumatoid arthritis

Public title

The effect of Saffron supplement on active rheumatoid arthritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: person with RA disease as American College of Rheumatology (ACR) criteria; aged over 18

years; having RA from 2 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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: Random assignment will be done by use of computer-generated random numbers. Blinding: Patients will be unaware of the type of intervention. investigator will not be aware of the intervention. Therefore, the trial will be run as double blind.

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

2017-07-12, 1396/04/21

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411323005

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

pain

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

visual analogue scales

2

Description

Morning stiffness

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Examintion

3

Description

Number of inflammated joints

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Examintion

4

Description

Number of swollen joints

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Examintion

5

Description

DAS28

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Examination

6

Description

IFN- γ

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

ELISA kit in pg / ml

7

Description

TNF- α

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

ELISA kit in pg / ml

8

Description

hs-CRP

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

ELISA kit in ng / ml

9

Description

ESR

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Westergern method

10

Description

MDA

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Using the kits and colorimetric method in umol / L

11

Description

TAC

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Using the kits and colorimetric method in umol / L

Secondary outcomes

1

Description

body mass index (BMI)

Timepoint

Before the intervention and then three months after the intervention

Method of measurement

Calculation / in kg / m²

Intervention groups

1

Description

Placebo group: For a period of 3 months (12 weeks), one tablet will contain 100 mg maltodextrin daily.

Category

Placebo

2

Description

Saffron powder group: One day, one tablet will contain 100 mg of saffron for 3 months (12 weeks).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Dr Fatemeh Shirani

Street address

Hazrat Rasool Akram Hospital, Niayesh Avenue, Sattar Khan 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 Seyed Ali Javad Mousavi

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

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

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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