Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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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Recruitment status

Recruitment complete

Funding source

Vice- chanceller 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 strickening 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 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
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 rheumathoid 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
Examintion

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
Street address
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