Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Saffron consumption on some mediator genes of immunity and inflammation in adult with active rheumatoid arthritis

Protocol summary

Summary

This study will examine the effect of Saffron supplement on the expression of some mediator genes of immunity and inflammation in patients with active rheumatoid arthritis referring to shariati 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. Random assignment will be done by use of computer-generated random numbers.Patients in case group will receive Saffron pill containing 100 mg Saffron powder once a day for 3 months and control patients will receive Placebo pill containing 100 mg " maltodextrin " once a day for 3 months. Placebo capsules are completely similar to the others and will be given randomly to Patients. Patients will be controlled by calling weekly and visiting monthly. for comparing two groups before after the 3 months intervention period clinical outcomes will be assessed and these tests will be operated on them: ROR-□t, T-bet,GATA3,Foxp3,PPAR-□, NF-kB, IL-17 AND IL-4 in two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707309472N15**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name
Naheed Aryaeian
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4750
Email address
aryaeian.n@iums.ac.ir

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 consumption on some mediator genes of immunity and inflammation in adult with active rheumatoid arthritis

Public title

The effect of Saffron supplement on active rheumatoid arthritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : diagnosis of rheumatoid arthritis as American College of Rheumatology (ACR) criteria;

patients with age 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 onset of an acute disease; migration ; any change in drug and treatment protocol that can cause omission from study.

Age
From **18 years** old to **70 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
Single

Other design features
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 1396.9411323004

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
ROR-t gene expression amount

Timepoint
before intervention AND 3 months after intervention

Method of measurement
real time PCR method in ΔΔCT

2

Description
PPAR- gene expression amount

Timepoint
before intervention AND 3 months after intervention

Method of measurement
real time PCR method in ΔΔCT

3

Description
FoxP3 gene expression amount

Timepoint
before intervention AND 3 months after intervention

Method of measurement
real time PCR method in ΔΔCT

4

Description
GATA3 gene expression amount

Timepoint
before intervention AND 3 months after intervention

Method of measurement
real time PCR method in ΔΔCT

5

Description
NF-kB gene expression amount

Timepoint
before intervention AND 3 months after intervention

Method of measurement
real time PCR method in ΔΔCT

6

Description
t-bet gene expression amount

Timepoint

before intervention AND 3 months after intervention

Method of measurement

real time PCR method in ΔΔCT

7

Description

Interleukin-17

Timepoint

before intervention AND 3 months after intervention

Method of measurement

ELISA kit in pg/ml

8

Description

Interleukin-4

Timepoint

before intervention AND 3 months after intervention

Method of measurement

ELISA kit in pg/ml

Secondary outcomes

1

Description

BMI

Timepoint

before intervention AND 3 months after intervention

Method of measurement

formula

Intervention groups

1

Description

Control groups: Patients that refer to hospital shariati who wish to cooperate and have inclusion criteria will receive 100 mg maltodextrin (100 mg tablet) for 3 months

Category

Placebo

2

Description

Intervention Group: Patients that refer to hospital shariatti who wish to cooperate and have inclusion criteria will receive 100mg of powdered saffron daily (by one 100 mg tablet) for 3 months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology research center of shariati hospital

Full name of responsible person

mehdi mahmoodi

Street address

south-karegar,jalal aleahmad st.shariati hospital

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

hemmat highway,sheikh fazlolahe noori avenue.Iran univesiy of medical sciences

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

Street address

School of health, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Postal code

Phone

+98 21 8670 4750

Fax

Email

n-aryaeian@sina.tums.ac.ir

Web page address

Person responsible for scientific 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

Street address
School of health, Iran University of Medical Sciences, Hemmat highway

City
Tehran

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Phone
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Fax

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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran univesity of medical sciences

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Dr Naheed Aryaeian

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Street address
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Web page address

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