Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation the effects of Saffron pill in comparison to placebo on rheumatoid arthritis disease activity level

Protocol summary

Summary

(1) Aim of study: Evaluation the effects of Saffron extract on rheumatoid arthritis disease activity in newly diagnosed patients. (2) Major inclusion and exclusion criteria: All the patients with completed informed consent form and with diagnosis of rheumatoid arthritis disease who didn't receive any treatment and with over 18 years old will be included in the study. (3) Study population and sample size: 60 patients with newly diagnosed Rheumatoid Arthritis. (4) Study Intervention: In intervention group, patients will receive Saffron pill containing 100 mg Saffron extract once a day for 4 months in addition to standard treatment including: 5 mg Prednisolone daily, 7.5 mg oral Methotrexate weekly, 5 mg Folic acid weekly, 400 IU Vitamin D daily, 800 mg Calcium daily, 70 mg Alendronate weekly. In the control group, patients will receive Placebo pill containing "Sunset" paint once a day for 4 months in addition to standard treatment the same as intervention group. (5) Primary outcomes: Disease activity level, in the beginning of study and 1, 2.5, and 4 months after study initiation, will be evaluated using determined formula for DAS28-ESR, which is on the basis of physical examination, ESR level, and patient self assessment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071218453N1**
Registration date: **2015-05-15, 1394/02/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-15, 1394/02/25

Registrant information

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Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effects of Saffron pill in comparison to placebo on rheumatoid arthritis disease activity level

Public title

Effect of Saffron on Rheumatoid Arthritis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: To have four criteria of ACR-1987 for Rheumatoid Arthritis; New patients who haven’t received any standard treatment up to the time of the study; Patients over 18 years old. Exclusion criteria: Pregnancy;

Breast-feeding; Diagnosed sensitivity to saffron; Diagnosed hepatic and renal diseases; Other comorbid rheumatologic diseases; Malignancies and/or active infections; Diagnosed psychological diseases.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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 committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Daneshgah street, Mashhad, Khorasan-Razavi, Iran

City

Mashhad

Postal code

Approval date

2014-05-24, 1393/03/03

Ethics committee reference number

922383

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Disease activity level according to DAS28-ESR score

Timepoint

Beginning of study - 1 month after beginning of study - 2.5 months after beginning of study - 4 months after beginning of study

Method of measurement

Using determined formula for DAS28-ESR which is according to physical examinations, ESR level, and patient self-assessment

Secondary outcomes

1

Description

HAQ-DI

Timepoint

Beginning of study - 1 month after beginning of study - 2.5 months after beginning of study - 4 months after beginning of study

Method of measurement

According to HAQ-DI questionnaire which is translated to Persian and its validation has been assessed

2

Description

EULAR response

Timepoint

1 month after beginning of study - 2.5 months after beginning of study - 4 months after beginning of study

Method of measurement

According to EULAR criteria table on the basis of DAS28-ESR score

3

Description

Saffron pill adverse effects

Timepoint

1 month after beginning of study - 2.5 months after beginning of study - 4 months after beginning of study

Method of measurement

According to check list containing known adverse effects of Saffron

Intervention groups

1

Description

Intervention group: Saffron pill containing 100 mg Saffron extract once a day for 4 months in addition to standard treatment including: - 5 mg Prednisolone daily - 7.5 mg oral Methotrexate weekly - 5 mg Folic acid weekly - 400 IU Vitamin D daily - 800 mg Calcium daily - 70 mg Alendronate weekly

Category
Treatment - Drugs

2

Description
Control group: Placebo pill containing "Sunset" paint once a day for 4 months in addition to standard treatment including: - 5 mg Prednisolone daily - 7.5 mg oral Methotrexate weekly - 5 mg Folic acid weekly - 400 IU Vitamin D daily - 800 mg Calcium daily - 70 mg Alendronate weekly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatic Diseases Research Center (RDRC), Ghaem Educational, Research and Treatment Center, Mashhad
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Mashhad University of Medical Sciences, Daneshgah street, Mashhad, Khorasan-Razavi, Iran
City
Mashhad
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 of Mashhad University of Medical Sciences
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
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Person responsible for scientific 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