Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Investigating the effect of crocin on the severity of fatigue, pain and quality of life in patients with multiple sclerosis

Protocol summary

Study aim
Determining the effect of crocin as a complementary drug with anti-inflammatory and antioxidant properties in the treatment MS patients.

Design
This study will be a parallel double-blind clinical trial, randomized in a simple block method in phases 2 and 3 on 40 patients with MS.

Settings and conduct
This study will be conducted in the neurology department and clinic of Ghaem Hospital. After visiting by the specialist doctor and according to inclusion criteria, the pills are randomly provided to the patient. All patients will sign an informed consent.The distribution of tablets is double-blind, and the specialist doctor and patients will not know.

Participants/Inclusion and exclusion criteria
Inclusion criteria : definitive diagnosis of MS by a neurologist visit, based on McDonald's criteria, MS patients with aged 18 to 50 (relapsing-remitting or RRMS), not having relapse attacks one month before the study, score 0 to 5 based on the scale of disability development status, fatigue intensity score equal to or higher than 4, feeling chronic pain in at least one of the body organs, receiving first and second line drugs treatment. exclusion criteria: suffering from other diseases, addiction to alcohol, narcotics and psychotropic substances, history of saffron allergy, pregnancy and breastfeeding, presence of infection and severe inflammation, motor disability score higher than 6, heavy daily exercise, use anti-inflammatory and antioxidant drugs as a supplement or Amantadine as an anti-fatigue drug, unwillingness to participate in the study or continue the treatment process.

Intervention groups
Intervention group: receiving crocin, who received a 15 mg crocin tablets daily for two months. Control group: Placebo recipients (placebo), who receive one placebo pills daily for two months.

Main outcome variables
Primary outcomes: fatigue and pain and quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130418013058N17**
Registration date: **2023-08-02, 1402/05/11**
Registration timing: **prospective**

Last update: **2023-08-02, 1402/05/11**
Update count: **0**

Registration date
2023-08-02, 1402/05/11

Registrant information

Name
Seyed Ahmad Mohajeri

Name of organization / entity
Pharmaceutical Research Center, School Of Pharmacy, Mashhad University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-12, 1402/07/20

Expected recruitment end date
2024-06-19, 1403/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of crocin on the severity of fatigue, pain and quality of life in patients with multiple sclerosis

Public title
Investigating the effect of crocin in multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of MS with neurologist visit, based on the McDonald diagnostic criteria, at least 6 months have passed since the diagnosis. Patients with relapsing-remitting MS or RRMS receiving first- and second-line MS disease therapy. No relapse attacks one month before of the study. Expression of willingness to participate in the study. 0 to 5 points based on expanded disability status scale. ā fatigue intensity score equal to or higher than 4 according to the Fatigue severity scale Having a feeling of chronic pain in at least one of the body organs and a score higher than 4 based on Numerical rating scale. MS patients who take first and second line drugs (dimethyl fumarate, Resigen, Betaferon, Triflunomide, Fingolimido Cinomer).
Exclusion criteria:
Suffering from other diseases such as (chronic diseases, heart failure, glands, breathing, liver, kidney, skeletal-muscular) and mental diseases and severe depression. Addiction to alcohol, drugs and psychedelics History of allergy to saffron Pregnancy and breastfeeding The presence of severe infection and inflammation, varicose veins, active thrombosis, damage to organs such as fractures. Motor disability score higher than 6 Getting any other serious diseases such as heart, liver and kidney diseases during treatment Do heavy exercise daily Any use of anti-inflammatory and antioxidant drugs as a supplement or Amantadine as an anti-fatigue drug Unwillingness to participate in the study or continue the treatment process
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
For each tablet container, four-digit codes will be Randomly labeled to Each Box by pharmacist . The Therapist will give it to the Patient Randomly without Knowledge of the Type of Medicine. Thus, the nature of each code will not be known until the analysis of the results.
Blinding (investigator's opinion)
Double blinded
Blinding description
Crocin and placebo tablets will be prepared in a similar shape, color, and size, stored in a dark container and coded by a pharmacist. The physician, researcher and patients will not be aware of the code printed on the container.
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 Science
Street address
Deputy of Science and Technology, Mashhad University of Medical Sciences, next to the Hoveizeh cinema, Daneshgah Avenue
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Approval date
2023-03-11, 1401/12/20
Ethics committee reference number
IR.MUMS.REC.1402.002

Health conditions studied

1

Description of health condition studied
MS or multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description

fatigue

Timepoint

Before and two months after the intervention

Method of measurement

MFIS fatigue assessment questionnaire

2

Description

pain

Timepoint

Before and two months after the intervention

Method of measurement

VAS or visual analog scale questionnaire

3

Description

Quality of life

Timepoint

Before and two months after the intervention

Method of measurement

Quality of Life Questionnaire Multiple Sclerosis Impact Scale (MSIS-29)

Secondary outcomes

1

Description

sexual desire

Timepoint

Before and two months after the intervention

Method of measurement

Men (International Index of Erectile Function) and women's (Female Sexual Function Index) sexual health questionnaire

Intervention groups

1

Description

Intervention group: who receive one 15 mg crocin tablet daily for two months.

Category

Treatment - Drugs

2

Description

Control group: Placebo recipients (placebo), who receive one placebo tablets daily for two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Department and Clinic of Ghaem Hospital

Full name of responsible person

Dr. Mohammad Ali Nahayati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

4011389

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available