

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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. A 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

Crocine 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

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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
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Sponsors / Funding sources

1

Sponsor
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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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. seyed Ahmad Mohajeri

Position

professor, PhD in Pharmacology, Faculty Member of Pharmacodynamics and Toxicology, School of Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**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