Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Efficacy of Crocin and Curcumin Combinational Capsule on the severity of fatigue, pain and quality of life in patients with multiple sclerosis

Protocol summary

Study aim
The effect of a crocin-curcumin combination formulation on quality of life, fatigue levels, and pain intensity in MS.

Design
randomized, double-blind, parallel-group, placebo-controlled, phase 2 clinical trial involving 40 patients. For randomization, a random number table generated by the Excel software's randomization function will be used.

Settings and conduct
At least 20 patients will be enrolled in each group.The drug and placebo will both be in the same shape and color, placed in identical containers, and assigned a code. The patient, physician, and researcher will be blinded to this code. The study site is the neurology department and clinic of Ghaem Hospital.

Participants/Inclusion and exclusion criteria
Definite diagnosis of multiple sclerosis confirmed by a neurologist, based on the McDonald criteria, with a minimum of 6 months since diagnosis and a disease duration of no more than 10 years. Gender: Both male and female. Patient age: 18 to 60 years. Patients with relapsing-remitting multiple sclerosis (RRMS) receiving first-line and second-line disease-modifying therapies. Absence of relapse one month prior to study enrollment. Willingness to participate in the study. Expanded Disability Status Scale (EDSS) score of 0 to 5. Fatigue Severity Scale (FSS) score equal to or greater than 4. Presence of chronic pain in at least one limb and a Numerical Rating Scale (NRS) pain intensity score greater than 4. Absence of underlying comorbidities. Patient compliance.

Intervention groups
Multiple sclerosis patients who meet the inclusion criteria, after receiving the necessary information and expressing their willingness to participate, will be enrolled in two treatment groups (receiving the crocin-curcumin combination drug) and control group (receiving placebo) by signing an informed consent form.

Main outcome variables
Pain intensity; Fatigue severity; Quality of life; Sexual function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130418013058N18**
Registration date: **2025-05-22, 1404/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-22, 1404/03/01**
Update count: **0**

Registration date
2025-05-22, 1404/03/01

Registrant information

Name
Seyed Ahmad Mohajeri

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

Country
Iran (Islamic Republic of)

Phone
+98 51 1882 3255

Email address
mohajeria@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-29, 1404/02/09

Expected recruitment end date

2026-10-31, 1405/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy of Crocin and Curcumin Combinational Capsule on the severity of fatigue, pain and quality of life in patients with multiple sclerosis

Public title

Crocin and Curcumin Effect on Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of multiple sclerosis confirmed by the neurologist, based on the McDonald criteria, with a minimum of 6 months since diagnosis and a disease duration of no more than 10 years. Patients with relapsing-remitting multiple sclerosis (RRMS) receiving first-line and second-line disease-modifying therapies. Absence of relapse one month prior to study enrollment. Willingness to participate in the study. Expanded Disability Status Scale (EDSS) score of 0 to 5. Fatigue Severity Scale (FSS) score equal to or greater than 4. Presence of chronic pain in at least one limb and a Numerical Rating Scale (NRS) pain intensity score greater than 4. Patients with multiple sclerosis receiving first-line and second-line disease-modifying therapies (dimethyl fumarate, reciGen, Betaferon, teriflunomide, fingolimod, glatiramer acetate). Absence of underlying comorbidities such as diabetes, cardiovascular diseases, and genetic disorders. Patient compliance: ability to participate in interviews and communicate feelings and experiences.

Exclusion criteria:

Presence of other underlying comorbidities (chronic diseases, cardiovascular, endocrine, respiratory, hepatic, renal, musculoskeletal disabilities), mental disorders, and severe depression. Addiction to alcohol, narcotics, and psychotropic substances. History of saffron or turmeric allergy. Pregnancy and lactation. Presence of severe infection and inflammation, varicose veins, active thrombosis, limb injuries such as fractures. Expanded Disability Status Scale (EDSS) score greater than 6. New onset of any other serious illness such as cardiac, hepatic, and renal diseases during treatment. Performance of strenuous daily exercise. Any use of anti-inflammatory and antioxidant drugs as supplements, or amantadine as an anti-fatigue medication. Unwillingness to participate in the study or continue the treatment process.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Each capsule container will be assigned a four-digit code using a random number table. These codes will be randomly labeled onto each container by the pharmacist. The therapist will randomly provide the containers to patients without knowledge of the medication type. Consequently, the nature of each code will remain unknown until the results are analyzed

Blinding (investigator's opinion)

Double blinded

Blinding description

Crocin-curcumin capsules and placebo capsules will be prepared with similar shape, color, and size, stored in dark containers, and coded by a pharmacist. The treating physician, researcher, and patient will be blinded to the codes on the aforementioned containers

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

Deputy of Science and Technology, Mashhad University of Medical Sciences, next to the Hoveizeh cinema, Daneshgah Avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2025-02-22, 1403/12/04

Ethics committee reference number

IR.MUMS.REC.1403.386

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
Modified Fatigue Impact Scale (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 function
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: During the two-month period, they will receive oral capsules containing a combination of 7.5 mg crocin and 150 mg curcumin twice daily (BID), totaling 15 mg crocin and 300 mg curcumin per day
Category
Treatment - Drugs

2

Description
Control group: Receiving placebo, with placebo capsules administered twice daily (BID) throughout the two-month period.
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
Street address
Ghaem Hospital, Ahmedabad Street.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3840 0001
Email
nahayati@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Research and Technology Vice-Chancellor, Qurashi Building, next to Hoveize Cinema, University St., Mashhad, Khorasan Razavi
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
TafaghodiM@mums.ac.ir
Grant name
Grant code / Reference number
4021527
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 Pharmacodynamy and Toxicology, School of Pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9188617871

Phone
+98 51 3882 3251

Email
mohajeria@mums.ac.ir

Person responsible for scientific 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 Pharmacodynamy and Toxicology, School of pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9188617871

Phone
+98 51 3882 3251

Email
mohajeria@mums.ac.ir

Person responsible for updating data

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 Pharmacodynamy and Toxicology, School of Pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Mashhad University of Medical Sciences, Vakil Abad Blvd., Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9188617871

Phone
+98 51 3882 3251

Email
mohajeria@mums.ac.ir

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