Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the effect of crocin on quality life, anxiety and depression in patients with multiple sclerosis in a placebo-controlled randomized double blind clinical trial

Protocol summary

Study aim
Determining the effectiveness of crocin on depression, anxiety and quality of life in patients with MS patients.

Design
This study will be a parallel triple-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 of Imam Khomeini Hospital. After the introduction of the patient by a specialist doctor and according to the inclusion criteria, tablets are randomly provided to the patients. At first visit, the informed consent form is signed by the patient. The distribution of tablets is random, three-blind, and the specialist doctor and the patient will not know how to divide the tablets.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definitive diagnosis of MS disease with a neurologist visit, and based on McDonald's criteria, patients with MS aged 18 up to 50 (recurrence-recovery or RRMS), not having relapse attacks one month before the study, expressing willingness to participate in the study, scoring 0 to 5.5 based on the Expanded Disability Status Scale (EDSS), patients with MS who use first and second line drugs in oral and injectable form, use of anxiety and depression category of drugs SSRIs are used. Exclusion Criteria:suffering from other diseases such as (chronic diseases, skeletal-muscular) and mental diseases and severe depression, addiction to alcohol, drugs and psychotropic substances, history of allergy to saffron, pregnancy and breastfeeding, presence of infection and severe inflammation, motor disability score higher than 6.

Intervention groups
Intervention group: who receive one 15 mg crocin tablet daily for two months. Control group: Placebo recipients (placebo), who receive one placebo tablet daily for two months.

Main outcome variables
Primary outcomes: anxiety, depression and quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221109056447N1**
Registration date: **2023-11-29, 1402/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-29, 1402/09/08**
Update count: **0**

Registration date
2023-11-29, 1402/09/08

Registrant information

Name
Samaneh Sepahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of crocin on quality life, anxiety and depression in patients with multiple sclerosis in a placebo-controlled randomized double blind clinical trial

Public title

Investigating the effect of crocin on patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of MS with neurologist visit, based on the McDonald diagnostic criteria. Patients with MS aged 18 to 50 (relapsing-remitting MS or RRMS). No relapse attacks one month before t the study. Obtaining 0 to 5.5 points based on the disability scale. Patients who take first and second line drugs in oral and injectable form (dimethyl fumarate, Resigen, Betaferon, Triflunomide, Fingolimido Sinomer). According to the specialist doctor, SSRI drugs such as fluoxetine, citalopram and sertraline are used as standard drugs for the treatment of anxiety and depression in these patients. Expression of willingness to participate in the study.

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. 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

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be in a simple method with the Excel software; numbers (or codes) will be created in Excel using the Random Number Generation option. These numbers will be prepared according to the sample size (number of patients) and according to the number of studied groups, which are two groups in this study, and as a result the numbers will be prepared in two column. First column of the random number table will be assigned to crocin group and the second one to placebo. The codes will be written on a piece of paper and put into an opaque envelope. The envelopes will be sealed and placed sequentially in a box and kept by researcher and physician. Envelopes and their code will be assigned sequentially to eligible participants in order of their arrival time. Thus, each code is not known until the results are analyzed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Crocin and placebo tablets are coded in dark boxes by a third party (the patient and the specialist doctor have no knowledge of how the pills are distributed) and are randomly given to the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Science

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Orjhans Street, Resalat Blvd.

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Approval date

2023-10-09, 1402/07/17

Ethics committee reference number

IR.UMSU.REC.1402.191

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

The effect of crocin on the anxiety intensity

Timepoint

Measuring anxiety intensity at the beginning of the study (before the intervention) and two months after the intervention.

Method of measurement

Beck's anxiety questionnaire.

2

Description

The effect of crocin on the depression Intensity

Timepoint

Measuring depression severity at the beginning of the study (before the intervention) and two months after the intervention.

Method of measurement

Beck's depression questionnaire.

3

Description

Effect of crocin on quality of life.

Timepoint

Measuring quality of life at the beginning of the study (before the intervention) and two months after the intervention.

Method of measurement

Questionnaire of quality of life of MS patients MsQoL-54 (Multiple Sclerosis Quality of Life-54)

Secondary outcomes

1

Description

Investigating the effect of crocin on periodic pain assessments

Timepoint

Examining periodic pain assessments at the beginning of the study (before the study) and two months after the intervention.

Method of measurement

Examining periodic pain assessments from the McGill Pain Questionnaire (MPQ)

Intervention groups

1

Description

Intervention group: who receive one 15 mg crocin tablet daily for two months. According to the diagnosis of a specialist doctor, for the treatment of anxiety and depression in these patients, SSRI drugs such as fluoxetine, citalopram and sertraline are used as standard drugs.

Category

Treatment - Drugs

2

Description

Control group: Placebo recipients (placebo), who receive one placebo tablets daily for two months.According to the diagnosis of a specialist doctor, for the treatment of anxiety and depression in these patients, SSRI drugs such as fluoxetine, citalopram and sertraline are used as standard drugs

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department and neurology clinic of Imam Khomeini hospital in Urmia

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Samaneh Sepahi

Position
Assistant professor of pharmaceutical sciences, Urmia university of medical sciences.

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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