Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of the effectiveness of crocin as a supplement in patients with refractory focal epilepsy in a randomized double-blind clinical trial

Protocol summary

Study aim

Investigating the effectiveness of crocin on patients with treatment-resistant focal epilepsy.

Design

The study is designed as a double blinded randomized clinical trial. There was 2 groups , one groups is crocin 15 mg/day and other is placebo (receive placebo tablet) for 3 months. table of random numbers will be used to code the drug packets. This study is conducted in the second phase of the clinical trial and as a pilot with a minimum sample size of 40 people (20 people in each group).

Settings and conduct

This study will be conducted in the office of Dr. Mustafa Asadollahi, specialist in fellowship neurology, also tablets will be produced from pure crocin at Mashhad Pharmacy School. The physician, researcher and patient will not be aware of distribution of tablets in crocin and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: using at least one fixed dose regimen of three anti-epileptic drugs, number of attacks in the 3 months before study were at least 5 attacks. Exclusion criteria: Pregnancy and breastfeeding, receiving crocin in the last two months, alcohol or drugs abuse, history of severe anaphylaxis or serious blood dyscrasia, suffering from psychiatric disorders or behavioral disorder, bipolar disorder, schizophrenia.

Intervention groups

Treatment group: patients with refractory focal epilepsy that receive 2 tablet of 15 mg/day of crocin for 3 months. control group : patients with refractory focal epilepsy that receive two Placebo tablet per day for 3 months.

Main outcome variables

The main symptom of epilepsy is a seizure. Examining the effective factors in reducing the number of epileptic attacks can be considered as a response to treatment. The main outcome is the effect of crocin as a complementary drug in the number of focal epilepsy attacks, which is measured by evaluating the change in the number of seizures; the response rate is 50%.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130418013058N16**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**

Registration date

2023-04-24, 1402/02/04

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

2023-04-30, 1402/02/10

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of crocin as a supplement in patients with refractory focal epilepsy in a randomized double-blind clinical trial

Public title

Evaluation of crocin in patients with refractory focal epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with refractory focal epilepsy based on the examination of a specialist doctor Patients should be taking at least one fixed-dose regimen of one to three anti-epileptic drugs The number of refractory focal epilepsy attacks in should be at least 5 attacks at 3 months before the study Written consent to participate No heart, kidney and liver diseases and not having blood diseases problems and coagulation diseases

Exclusion criteria:

Female patients were excluded if they were pregnant, lactating, or of childbearing age and not using approved methods of contraception. Patients were excluded if they had previously received crocin or participated in any other research trial within the previous 2 months. Patients were also excluded from the study if they had a history of substance abuse such as alcohol or drugs during the sample collection period. Any medical conditions that may endanger the patient's health or compromise the patient's ability to participate in the trial will be excluded from the study. Have a history of severe anaphylaxis or serious blood dyscrasia Any other significant clinical condition, or recent chronic use of non-AED medications that may interfere with drug absorption, distribution, metabolism, or excretion. Regular treatment with one of the following drugs that affect the CNS. such as neuroleptics , monoamine oxidase (MAO) inhibitors, barbiturates (except when taken as concomitant anticonvulsant therapy), or narcotic analgesics within 4 weeks prior to enrollment. Suffering from psychiatric disorders or behavioral disorders, bipolar disorder, schizophrenia or suicidal tendencies or any other mental disorder. Life-limiting conditions that cause the patient to be unable to complete the course of treatment and need another drug Allergy to saffron Suffering from any other serious diseases such as heart, liver and kidney diseases during treatment

Age

From **16 years** old to **70 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

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-12-17, 1401/09/26

Ethics committee reference number

IR.MUMS.REC.1401.340

Health conditions studied

1

Description of health condition studied

Focal epilepsy disease

ICD-10 code

G96.8

ICD-10 code description
Other specified disorders of central nervous system

Primary outcomes

1

Description
Number of focal epileptic seizures
Timepoint
After 3 months of medication
Method of measurement
Changes in seizure number and response rate

Secondary outcomes

1

Description
Depression and anxiety disorders
Timepoint
3 months after taking the drug
Method of measurement
Beck questionnaire

Intervention groups

1

Description
Intervention group: receiving crocin, who received two 15 mg crocin tablets daily for three months.
Category
Treatment - Drugs

2

Description
Control group: Placebo recipients (placebo), who receive two placebo pills daily for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
The office of Dr. Mustafa Asadollahi, specialist in neurology, epilepsy fellowship
Full name of responsible person
Dr. Mustafa Asadollahi
Street address
Riyazi Square, Safieh, Yaz.
City
Yazd
Province
Yazd
Postal code
983538224000
Phone
+98 35 3822 9105
Email
zeinab.hadad1997@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayor Mobarhan
Street address
Khorasan, Razavi, Mashhad, University St., next to Hoize Cinema, Qurashi Building, Research and Technology Vice-Chancellor
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
Email
ghayourm@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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
17871 91886
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 3251 3882
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
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 3251 3882
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