

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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	• Investigator
Trial completion date empty	Sample size Target sample size: 40
Scientific title Evaluation of the effectiveness of crocin as a supplement in patients with refractory focal epilepsy in a randomized double-blind clinical trial	Randomization (investigator's opinion) Randomized
Public title Evaluation of crocin in patients with refractory focal epilepsy	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.
Purpose Supportive	Blinding (investigator's opinion) Double blinded
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	Blinding description Crocinn 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
Age From 16 years old to 70 years old	Health conditions studied 1 Description of health condition studied Focal epilepsy disease
Gender Both	ICD-10 code G96.8
Phase 2-3	
Groups that have been masked • Participant • Care provider	

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Khorasan, Razavi, Mashhad, University St., next to Hoize Cinema, Qurashi Building, Research and Technology Vice-Chancellor

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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 Pharmacodynamics and Toxicology, School of

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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