Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of crocin in the treatment of cystoid macular edema secondary to retinitis pigmentosa : randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of crocin in the treatment of macular cystoid edema secondary to retinitis pigmentosa

Design
Clinical trial with control and intervention group, double-blind, randomized, phase 2-3 on 20 patients. Pass software was used for randomization.

Settings and conduct
The location of the research is Khatam Al-Anbia Specialized Ophthalmology Hospital. Patients who meet the criteria to enter the project, after obtaining informed consent, entered the project and were randomly divided into two intervention and control groups. Patients in the intervention group take one 15 mg crocin tablet daily along with Ketorolac and Dorzolamide eye drops and in the control group one daily They take a number of placebo tablets along with Ketorolac and Dorzolamide eye drops. At the beginning of the study, the central thickness of the macular was determined using OCT BCVA is measured and recorded in all patients. Then macular OCT and BCVA are repeated monthly for three months. Finally, at the end of three months, thickness changes Macular center in OCT and BCVA will be compared in two intervention and control groups Patients and assessors are blinded in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with typical retinitis pigmentosa with an increase in the central thickness of the macula Exclusion criteria:They are during pregnancy and breastfeeding.

Intervention groups
Patients in the intervention group take one 15 mg crocin tablet daily along with ketorolac and dorzolamide eye drops and in the control group one daily They take placebo tablets along with ketorolac and dorzolamide eye drops.

Main outcome variables
The amount of CMT and The size of the cysts in OCT at the beginning of the study before the intervention and at the end of the first, second and third month

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201219049753N2**
Registration date: **2022-09-12, 1401/06/21**
Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**
Update count: **0**

Registration date
2022-09-12, 1401/06/21

Registrant information

Name
Ghodsieh Zamani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3728 1401

Email address
zamanigh@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-22, 1401/06/31

Expected recruitment end date
2023-02-19, 1401/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of crocin in the treatment of cystoid macular edema secondary to retinitis pigmentosa : randomized clinical trial

Public title
Evaluation of the effect of crocin in the treatment of cystoid macular edema secondary to retinitis pigmentosa

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with typical retinitis pigmentosa with increased central macular thickness They have not received treatment for this condition in the last 3 months They have the ability to understand the study and the power to choose to participate in the study.

Exclusion criteria:
History of diabetes Recent ocular surgery pregnancy and lactation period History of taking drugs that cause macular edema in the last 3 months Suffering from other eye diseases that lead to macular cystoid edema

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done using PASS software. In this way, the studied groups (coded) and the number of patients in each group will be entered into the software and a random sequence will be generated. The sequences are placed in closed envelopes in the same order as they were produced by a person who is not in the course of the study. In such a way that the contents of the envelopes cannot be seen from the outside. The envelopes are numbered. Then for each patient who meets the entry criteria An envelope will be opened and based on the contents of the envelope, a person will be entered into the intervention or control group. All steps of sequence generation and allocation of patients to groups and concealment of allocation will be done by someone who is not in the course of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients, clinical care and outcome assessors are kept blind. And they are not aware of the content of drug packages and the allocation of patients to intervention and control groups. The drug and placebo are similar in terms of color, shape and smell.

Placebo
Used

Assignment
Parallel

Other design features
The study includes two intervention and control groups, both groups receive the conventional treatment for cystoid macular edema, but in the intervention group, crocin tablets are also prescribed in addition to the conventional treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences Faculty of Medicine

Street address
Ethics committee, Medical sciences faculty, Pardis, Vakil abad blvd.

City
Mashhad

Province
Razavi Khorasan

Postal code
91735951

Approval date
2022-04-18, 1401/01/29

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.072

Health conditions studied

1

Description of health condition studied
Retinitis pigmentosa

ICD-10 code
H35.5

ICD-10 code description
Hereditary retinal dystrophy

Primary outcomes

1

Description
The CMT in OCT

Timepoint
The central thickness of the macula in OCT at the beginning of the study before the intervention and at the end of the first, second and third month

Method of measurement
Macular OCT

2

Description
size of cysts in the macula oct
Timepoint
At the beginning of the study before the intervention and at the end of the first, second and third month
Method of measurement
macula oct

Secondary outcomes

1

Description
Best corrected visual acuity (BCVA)
Timepoint
Best corrected visual acuity (BCVA) at the beginning of the study before the intervention and at the end of the first, second and third month
Method of measurement
Optometry

2

Description
Liver function tests
Timepoint
before the intervention and at the end of the study
Method of measurement
chemistry analyzer

3

Description
kidney function tests
Timepoint
before the intervention and at the end of the study
Method of measurement
chemistry analyzer

4

Description
Fasting blood lipid profile
Timepoint
before the intervention and at the end of the study
Method of measurement
chemistry analyzer

5

Description
fasting blood sugar
Timepoint
before the intervention and at the end of the study
Method of measurement
chemistry analyzer

6

Description
complete blood count
Timepoint
before the intervention and at the end of the study
Method of measurement
hematology analyzer

Intervention groups

1

Description
Intervention group :Patients with typical retinitis pigmentosa, over 18 years of age, who have macular cystoid edema (CMT above 296 microns in OCT or the presence of cysts in OCT) and meet the conditions for entering the study after an educational session about RP disease and complications Prescription drugs, side effects and how to use them, crocin tablets at the rate of 15 mg daily orally are started for them. In addition to crocin tablets, they also receive the conventional treatment of this condition, which is ketorolac and dorzolamide eye drops. The duration of treatment is three months. Crocin tablets contain the active ingredient crocin, the most important active ingredient in saffron.This drug is produced in poyesh daroye Sina Company
Category
Treatment - Drugs

2

Description
Control group: patients with typical retinitis pigmentosa, over 18 years of age, who have macular cystoid edema (CMT above 296 microns in OCT or the presence of a cyst in OCT) and meet the conditions for entering the study after an educational session about RP disease and complication , prescription drugs, side effects and how to use them are treated with ketorolac and dorzolamide eye drops and placebo. The duration of treatment is three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al Anbia Specialized Ophthalmology Hospital, Mashhad
Full name of responsible person
Mehdi eslami shoabjareh
Street address
No. 4, Kafaei St
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Email

mehdi1989eslami@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid ghayour mobarhan

Street address

Daneshgah Street, next to Hoveizeh Cinema, University of Medical Sciences, 3rd floor

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Province

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GhayourM@mums.ac.ir

Grant name

Grant code / Reference number

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

Mehdi eslami shoabjareh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehdi eslami shoabjereh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals.

When the data will become available and for how long
The start of the access period is after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions can have access.

Under which criteria data/document could be used
They can use the data to get acquainted with the type of data classification and statistical analysis.

From where data/document is obtainable
Sending an email to the researcher in charge of the study zamanigh@mums.ac.ir

What processes are involved for a request to access data/document
The request will be sent via an email to the researcher in charge of studying, and after reviewing the request by the research team and final approval, the data will be sent within a month.

Comments