

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Measurement of Crostin serum level after administration of Crocina tablet using HPLC technique

Protocol summary

Study aim

Measurement of Crostin serum level after administration of 15mg Crocina

Design

Field trial, pragmatic, without blinding.

Settings and conduct

After obtaining informed consent, one crocin tablet made by Sami Saz company containing 15 mg of crocin will be administered orally during the trial to 5 healthy male volunteers. In the next step, blood sampling will be done at 0, 30, 60, 90, 120, 180 and 240 minutes after drug administration. blood serum will be separated with a centrifuge at 5000 rpm for 20 minutes. In the next step, crostin is extracted from the serum and prepared for injection into the HPLC device. Analysis of crostin in blood will be done by HPLC. The concentration curve will be drawn in terms of time, and the pharmacokinetic parameters including the maximum concentration, the time required to reach the maximum concentration, the area under the concentration graph in terms of time and the half-life time will be calculated.

Participants/Inclusion and exclusion criteria

Entry conditions: Patient willingness to participate in the study, Age above 18 years, No addiction to narcotics and sedatives and alcohol, No history of mental illness, not using anticoagulants, Absence of diabetes, Absence of underlying disease; Non-entry conditions: Hemodynamic instability in participant, history of, Cardiopulmonary resuscitation in participant, past medical history of admission in the intensive care unit, abnormal liver tests (AST, ALT, CBC), abnormal kidney tests (U/A, BUN, Cr)

Intervention groups

One tablet of Crocina (15 mg) made by Samisaz Company is given orally to healthy people who do not take any other medicine.

Main outcome variables

blood concentration of crocetin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130507013263N2**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 1882 3255

Email address

hadizadehf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Measurement of Crostin serum level after administration

of Crocina tablet using HPLC technique

Public title

Measurement of Crostin serum level after administration of Crocina tablet using HPLC technique

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Patient willingness to participate in the study
Age above 18 years
No addiction to narcotics, sedatives and alcohol
No history of mental illness, no use of anticoagulants
Absence of diabetes
Absence of underlying disease

Exclusion criteria:

Hemodynamic instability in participant history of
Cardiopulmonary resuscitation in participant past
medical history of admission in the intensive care unit
abnormal liver tests (AST, ALT, CBC)
abnormal kidney tests (U/A, BUN, Cr)

Age

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

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

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

school of Pharmacy, Mashhad University of Medical Sciences, Azadi Sq., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2022-04-09, 1401/01/20

Ethics committee reference number

IR.MUMS.REC.1401.016

Health conditions studied

1

Description of health condition studied

Evaluation of the concentration-time curve of the a Crostin in healthy people

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of crostin blood concentration

Timepoint

Blood sampling will be done at 0, 30, 60, 90, 120, 180 and 240 minutes after drug administration.

Method of measurement

Determination of crostin blood concentration by HPLC (High-performance liquid chromatography) system

Secondary outcomes

empty

Intervention groups

1

Description

Administration of one crocin tablet made by Samisaz company containing 15 mg of crocin orally.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Pharmacy, Mashhad

Full name of responsible person

Farzin Hadizadeh

Street address

School of Pharmacy, Campus of University, Azadi Sq., Mashhad

City

mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1128

Fax

+98 51 3882 3251

Email

hadizadehf@mums.ac.ir

Web page address

<https://medchimdept.mums.ac.ir/member/aza-group>

Sponsors / Funding sources

1

Sponsor

Grant name

Grant code / Reference number

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

empty

Title of funding source

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzin Hadizadeh

Street address

School of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1128

Fax

+98 51 3180 1128

Email

hadizadehf@mums.ac.ir

Grant name

Grant code / Reference number

4001501

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

Farzin Hadizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Phone

+98 51 3180 1128

Email

hadizadehf@mums.ac.ir

Web page address

<https://medchimdept.mums.ac.ir/member/aza-group>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farzin Hadizadeh

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Contact

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Co-worker of proposal. Hossein Kamali and Faezeh Ghorbanzadeh and Mojgan Nejabat

Under which criteria data/document could be used

-

From where data/document is obtainable

Refer to me Farzin Hadizadeh. contact us: hadizadehf@mums.ac.ir

What processes are involved for a request to access data/document

-

Comments

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