

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of therapeutic effects of Crocin in reducing progression of diabetic nephropathy: A randomized triple-blind placebo-controlled trial

Protocol summary

Study aim

Evaluation of the therapeutic effects of crocin on the reduction of diabetic nephropathy in patients with diabetes mellitus and its comparison with placebo consumption

Design

this study is a prospective, triple-blind, randomized controlled clinical trial, 44 patients will randomly assign to control or intervention group. Crocin 15 mg and placebo tablets will pack in similar bottles and each bottle will have a different code. The nephrologist, student in charge of completing the questionnaires and the patient will not be notified of any grouping. The patients will asked to take their medications once a day for 90 days

Settings and conduct

Yazd Diabetes Research Center

Participants/Inclusion and exclusion criteria

inclusion criteria: age 18 years or older_A history of type 2 diabetes for at least 5 years, as defined by the WHO in 1985_fasting urine alb/cr ratio of 30 or higher on 2 separate occasions within the past 3 months_HbA1C less than 8_blood pressure less than 160/100_Srcr levels less than or equal to 2_treatment of hyperglycemia with (but not limited to) an oral hypoglycemic agent or insulin_treatment of hypercholesterolemia with (but not limited to) a statin Exclusion criteria: GFR less than 30_chronic heartfailure with New York Heart Association class III or IV_alcohol dependency or cigarette smoking_use of nsoids and antioxidant supplements within 3 months prior to enrollment in the study_Recent stroke, active cancer, anemia_recurrent urinary tract infection_pregnancy and lactation_Drug intolerance_Serious medical conditions in which the patient is unable to attend regular visits_Mental conditions that prevent conscious consent to enter the study or follow the study protocol

Intervention groups

Intervention group: 15 mg crocin per day and control

group: placebo

Main outcome variables

Changes in FBS, HgA1c, BUN, SrCr, 24-h urinary protein, UACR, blood levels of TGF- β

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N4**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Fatemeh Saghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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f.saghafi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of Crocin in reducing progression of diabetic nephropathy: A randomized triple-blind placebo-controlled trial

Public title

Evaluation of therapeutic effects of Crocin in reducing progression of diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age 18 years or older A history of type 2 diabetes for at least 5 years, as defined by the WHO fasting urine albumin/creatinine ratio of 30 mg/g or higher on two separate occasions within the past 3 months HbA1C less than 8 blood pressure less than 160/100 Serum creatinine levels less than or equal to 2 mg/dL treatment of hyperglycemia with (but not limited to) an oral hypoglycemic agent or insulin treatment of hypercholesterolemia with (but not limited to) a statin

Exclusion criteria:

GFR less than 30 mL/min/1.73 m² chronic heart failure with New York Heart Association class III or IV alcohol dependency or cigarette smoking use of one of certain specified medications within 3 months prior to enrollment in the study (nonsteroidal anti-inflammatory agents and antioxidant supplements, including vitamin E, vitamin C, fish oil extracts [omega-3 fatty acids], green tea preparations, pomegranate extracts, and grape extracts Recent stroke, active cancer, anemia recurrent urinary tract infection pregnancy and lactation Drug intolerance Serious medical conditions in which the patient is unable to attend regular visits include severe cardiovascular disease such as angina or heart attack. Mental conditions that prevent conscious consent to enter the study or follow the study protocol

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

the patients will be randomly divided into two groups of

intervention and control using the permutation blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding will perform on patients, clinical caregivers, including physicians and nurses, as well as variables assessors and data analysts

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

faculty of ethics of medical sciences - shahid sadoughi university of medical sciences

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Gomnam shohada boulevard - shahid sadoughi university of medical sciences

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8915173143

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.085

Health conditions studied**1****Description of health condition studied**

diabetic nephropathy

ICD-10 code

E11.21

ICD-10 code description

Type 2 diabetes mellitus with diabetic nephropathy

Primary outcomes**1****Description**

Fasting blood sugar levels

Timepoint

Before and after intervention

Method of measurement

blood sample

2

Description

glycosylated hemoglobin

Timepoint

Before and after intervention

Method of measurement

blood sample

3

Description

, Blood urea nitrogen (BUN)

Timepoint

Before and after intervention

Method of measurement

blood sample

4

Description

serum creatinine

Timepoint

Before and after intervention

Method of measurement

blood sample

5

Description

24-hour urinary protein

Timepoint

Before and after intervention

Method of measurement

blood sample

6

Description

urinary albumin-creatinine ratio (UACR),

Timepoint

Before and after intervention

Method of measurement

blood sample

7

Description

blood levels of TGF- β

Timepoint

Before and after intervention

Method of measurement

blood sample

Secondary outcomes

1

Description

life quality

Timepoint

Before and after intervention

Method of measurement

questionnaire

2

Description

adverse effects

Timepoint

Before and after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: take a 15 mg crocin tablet made by pouyesh darou sina company once daily for 90 days.

Category

Treatment - Drugs

2

Description

Control group: take a placebo tablet made by pouyesh darou sina company once daily for 90 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

yazd Diabetes Research Center

Full name of responsible person

Behzad Kafami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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
 Yazd 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
 Yazd University of Medical Sciences
Full name of responsible person
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 University student
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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