Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of crocin and saffron on glycemic control in type 2 diabetic patients; a double blind placebo controlled randomized clinical trial.

Protocol summary

Summary

Diabetes is one of the major metabolic disorders. The aim of this study was to evaluate the effect of saffron and crocin as agents with antioxidant properties for the treatment diabetes mellitus. This project can help to introduce crocin as an anti-diabetic drug. The methods used in this study include: 1. Extraction of saffron with water-alcohol extraction method, 2. Crystallization, 3-Producing tablets of crocin with direct-press. The number of patients is 180 who are divided into 3 groups: group 1 includes 60 type 2 diabetic patients that receive 15 mg/day crocin. Group 2 is 60 patients with type 2 diabetes mellitus that receive saffron with dose 15 mg per day. And group 3 includs 60 type 2 diabetic patients who use placebo. Patients will be enrolled after obtaining informed consent. Patients in 3 groups are under the supervision of an endocrinologist for 3 months. Once before and after the intervention, the clinical tests including fasting blood sugar will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101713058N3**
Registration date: **2015-12-27, 1394/10/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-27, 1394/10/06

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

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2017-02-17, 1395/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of crocin and saffron on glycemic control in type 2 diabetic patients; a double blind placebo controlled randomized clinical trial.

Public title

Effects of crocin and saffron on type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult patients (18 ≤) with type 1 and 2 diabetes؛ Patients with uncontrolled type 2 diabetes mellitus, and HbA1c> 7-7.5؛ Patients who have the ability to understand overview of the study, treatment and possible side effects؛Filling the consent form.
Exclusion criteria: Patients suffering from CKD, and Liver disease, and patients with pregnancy and breast-feeding؛Incidence of any side effects in which the patient

cannot continue to study.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

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Postal code

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

931153

Health conditions studied

1

Description of health condition studied

Diabetic type 2

ICD-10 code

E10,E14

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

every week

Method of measurement

glucometer

Secondary outcomes

1

Description

HbA1C

Timepoint

Before intervention,and three months later

Method of measurement

Blood test

Intervention groups

1

Description

control group: Placebo tablet.

Category

Treatment - Drugs

2

Description

Intervention: Group1: Patients With 15 mg per Day Of saffron. Group 2: Patients With 15 mg per Day Of Crocin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital of Mashhad

Full name of responsible person

Dr.Shokofeh Bonakdaran

Street address

Taghi Abad Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Dr.Seyed Ahmad Mohajeri

Street address

Between shahis Javan and Shahid Al-Shahidi,Shahid

Fakori Blvd., Mashhad.

City

Mashahad

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 Science

Proportion provided by this source

100

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

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

PhD in Pharmacology, Faculty Member of Pharmacodynamy and Toxicology, School of Pharmacy and Targete

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Targeted Drug Delivery Research Center, School of Pharmacy, Mashhad University of Medical Sciences,

Full name of responsible person

Samaneh Sepahi

Position

PhD By Research Student

Other areas of specialty/work

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sepahis931@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty