

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effects of crocin on nicotine dependence, depression, anxiety and metabolic biomarkers in cigarette smokers

Protocol summary

Study aim

The aim of this study is to determine the effects of crocin on nicotine dependence, depression, anxiety and metabolic biomarkers in cigarette smokers.

Design

Clinical trial with control group, parallel groups, double-blind (both patients and researchers), randomized, 60 patients, phase 2

Settings and conduct

Population and sample size: 60 eligible cigarette smokers and referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Time of intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cigarette smokers and aged 17 to 50 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention: Patients will be assigned to receive either crocin (n=30) or placebo (n=30).

Main outcome variables

Nicotine dependence; depression; anxiety (primary outcome) and metabolic biomarkers (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N11**

Registration date: **2021-12-23, 1400/10/02**

Registration timing: **prospective**

Last update: **2021-12-23, 1400/10/02**

Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of crocin on nicotine dependence, depression, anxiety and metabolic biomarkers in cigarette smokers

Public title

Effect of crocin in cigarette smokers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Smoking dependence Age of 17 to 50 years old Complete informed consent

Exclusion criteria:
Unwillingness to cooperate Taking crocin, anti-inflammatory and antioxidant supplements during the last 3 months before the intervention. History of metabolic diseases including diabetes, hypertension, thyroid, and cardiovascular disease. Pregnant women Positive urine test for morphine, methamphetamine and cannabis Use of psychiatric and neurological drugs such as benzodiazepines and antidepressants

Age
From **17 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups for example: the even numbers are for intervention group and the odd numbers are for the placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2021-12-06, 1400/09/15

Ethics committee reference number

IR.KAUMS.REC.1400.048

Health conditions studied

1

Description of health condition studied

Nicotine dependence in cigarette smokers

ICD-10 code

F17.21

ICD-10 code description

Nicotine dependence, cigarettes

Primary outcomes

1

Description

Nicotine Dependence Syndrome Scale

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

2

Description

Depression beck score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

3

Description

Anxiety beck score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Total glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

6

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

7

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

8

Description

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

9

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

10

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

11

Description

VLDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

12

Description

LDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: In this group of patients (n=30) will be requested to take two crocin tablets daily for 12

weeks (each tablet contain 15 mg crocin). The crocin tablets will be produced in the pharmacy faculty of Mashhad University of Medical Sciences from saffron.

Category

Treatment - Drugs

2**Description**

Control group: In this group of patients (n=30) will be requested to take two placebo tablets daily for 12 weeks. The placebo tablets (Contain Avicel) will be produced in the pharmacy faculty of Mashhad University of Medical Sciences.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gholabchi Clinic (Shahid Beheshti and Matini hospital)

Full name of responsible person

Amir Ghaderi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan 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

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Amir Ghaderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Ph.D of addiction

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Amir Ghaderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Ph.D of addiction

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Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Amir Ghaderi
Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Dr. Amir Ghaderi is committed to presenting all the achievements of the project in accordance with the framework of the National Institute for Medical Research Development in the Islamic Republic of Iran.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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