Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The Effects of curcumin on clinical and metabolic signs in cigarette smokers

Protocol summary

Study aim
The aim of this study is to determine the effects of curcumin 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, 70 patients, phase 2

Settings and conduct
Population and sample size: 70 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 curcumin (n=35) or placebo (n=35).

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: **IRCT20170420033551N12**
Registration date: **2022-05-26, 1401/03/05**
Registration timing: **prospective**
Last update: **2022-05-26, 1401/03/05**
Update count: **0**

Registration date
2022-05-26, 1401/03/05

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
2022-06-19, 1401/03/29

Expected recruitment end date
2022-07-31, 1401/05/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of curcumin on clinical and metabolic signs in cigarette smokers

Public title
Effect of curcumin in cigarette smokers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Smoking dependence (Fagerstrom test score more than 4) Age of 17 to 50 years old Complete informed consent

Exclusion criteria:

Unwillingness to cooperate Taking curcumin, 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: **70**

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

Research Ethics Committees of Faculty of Medicine & Dentistry- Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8814187159

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.017

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=35) will be requested to take two Sina Curcumin capsules daily

for 12 weeks (each capsules contain 40 mg curcumin). The Sina Curcumin capsules will be produced in the Nano Sina Elixir Company from curcuma.

Category

Treatment - Drugs

2

Description

Control group: In this group of patients (n=35) will be requested to take two placebo capsules daily for 12 weeks. The placebo capsules (Contain Starch) will be produced in the Nano Sina Elixir Company.

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

Street address

Kashan

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Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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Grant name

Grant code / Reference number

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

No

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

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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
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Full name of responsible person
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Position
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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