# 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

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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

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## Person responsible for updating data

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**Other areas of specialty/work**
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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