

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Clinical trial of the effect of curcuminoids supplementation compared with the placebo on mental health parameters and metabolic profiles in methadone maintenance treatment patients

Protocol summary

Study aim

The aim of this study is to determine the effects of curcuminoids supplementation on mental health parameters and metabolic profiles in methadone maintenance treatment patients

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: Among patients under methadone maintenance treatment referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, 90 patients will be selected according to inclusion and exclusion criteria. 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: Patients on methadone maintenance treatment and aged 18 to 60 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention group: capsule contains 80 mg curcuminoids (Zahravi, Tabriz, Iran), daily, for 12 weeks orally. Control group: curcuminoids placebos capsule (Barij essence, Kashan, Iran), daily, for 12 weeks orally.

Main outcome variables

Depression; anxiety; sleep quality (primary outcome) and fasting plasma glucose; Insulin; triglycerides; total cholesterol; HDL; Hs-CRP; total antioxidant; glutathione; malondialdehyde (secondary outcome).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N8**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **retrospective**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 771 7435

Email address

ghaderi-am@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-05, 1398/04/14

Expected recruitment end date

2019-08-05, 1398/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of curcuminoids supplementation compared with the placebo on mental health parameters and metabolic profiles in methadone maintenance treatment patients

Public title

Effect of curcuminoids supplementation in treatment of methadone maintenance treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under methadone maintenance treatment
Individuals aged 18 to 70 years

Exclusion criteria:

Unwillingness to cooperate
Suicide attempts within the past 12 months or either suicidal ideations or psychotic symptoms in the past 6 months as determined by a study physician
Current opioid, alcohol or sedative physical dependence or cocaine dependence
Major cardiovascular disorder
Present or recent use (within 2 weeks) of over-the-counter or prescription drug that would be expected to have major interaction with curcuminoid
Metabolic diseases

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

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 in the same packaging at the Barij Essence pharmaceutical company. 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

2019-06-30, 1398/04/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.036

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Depression

Timepoint

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

Method of measurement

Beck Depression Inventory (BDI)

2

Description

Anxiety

Timepoint

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

Method of measurement

Beck Anxiety Inventory (BAI)

3

Description

Sleep quality

Timepoint

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

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

1

Description

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

7

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

8

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

9

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: capsule contains 80 mg curcuminoids (Zahravi, Tabriz, Iran), daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: curcuminoids placebos capsule (Barij essence, Kashan, Iran), daily, for 12 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Gholabchi Clinic
Full name of responsible person
Hamid Reza Banafshe
Street address
Shahid Rajaei Avenue, Kashan
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Isfahan
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banafsseh.hr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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banafshe57@hotmail.com

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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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Position

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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