

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effects of vitamin D supplementation on mental health parameters, oxidative stress and inflammatory biomarkers in cigarette smokers

Protocol summary

2019-07-15, 1398/04/24

Study aim

The aim of this study is to determine the effects of vitamin D supplementation on mental health parameters, oxidative stress and inflammatory biomarkers in cigarette smokers.

Design

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

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/Inclusion and exclusion criteria

Inclusion criteria: Cigarette smokers and aged 17 to 60 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

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

Main outcome variables

Mental health parameters (primary outcome), oxidative stress and inflammatory 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: **IRCT20170420033551N7**

Registration date: **2019-07-15, 1398/04/24**

Registration timing: **retrospective**

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

Registration date

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of vitamin D supplementation on mental health parameters, oxidative stress and inflammatory biomarkers in cigarette smokers

Public title

Effect of vitamin D supplementation in cigarette smokers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Smoking dependence Age of 17 to 60 years old

Exclusion criteria:

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 Metabolic diseases such as diabetes and neurological diseases such as epilepsy Unwillingness to cooperate Current severe depression and mania psychosis

Age

From **17 years** old to **60 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

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<40 and ≥40 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo has been used to achieve masking of participants and investigators. The researchers and patients will be concealed until the final analyses by a trained staff.

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

2019-06-08, 1398/03/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.026

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

Depression beck score

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Questionnaire

2

Description

Anxiety beck score

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

HDL

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

Total cholesterol

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Triglycerides

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Enzymatic kit

6

Description

Insulin

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Elisa kit

7

Description

Nitric oxide

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Spectrophotometry

8

Description

Hs-CRP

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Elisa kit

9

Description

Total glutathione

Timepoint

At the beginning of the study and 24 weeks after intervention

Method of measurement

Spectrophotometry

10

Description

Malondialdehyde

Timepoint

At the beginning of the study and 24 weeks after intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: 50000 IU vitamin D (Zahravi, Tabriz, Iran), once every 2 weeks, for 24 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), once every 2 weeks, for 24 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Gholabchi Clinic

Full name of responsible person

Hamid Reza Banafshe

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Shahid Rajaei 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

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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

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Ph.D.

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Person responsible for updating data

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Name of organization / entity

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Amir Ghaderi

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Latest degree

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Ph.D of addiction

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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