Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
2019-07-15, 1398/04/24

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
Isfehan

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
Street address
Shahid Rajaee Avenue, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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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 updating data

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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