Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Vitamin D Supplementation on Cognitive Functions in Patients Receiving Maintenance Methadone Treatment

Protocol summary

Study aim
The aim of this study is to determine the effects of vitamin D supplementation on cognitive functions 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: 70 patients with maintenance methadone treatment of eligible and referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

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: Not living in Kashan, Taking vitamin D, multivitamin-mineral, and antioxidant supplements during the last 3 months before the intervention.

Intervention groups
Patients will be assigned to receive either vitamin D (n=35) or placebo (n=35). Vitamin D and placebos capsules are similar in shape and size.

Main outcome variables
Cognitive functions (primary outcome), depression and anxiety (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2017101133079N4**
Registration date: **2017-10-12, 1396/07/20**
Registration timing: **retrospective**
Last update: **2019-09-17, 1398/06/26**
Update count: **1**

Registration date
2017-10-12, 1396/07/20

Registrant information

Name
Morad Rasouli-Azad

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 989355392455

Email address
rasouliazad-m@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date
2017-04-04, 1396/01/15

Expected recruitment end date
2017-05-05, 1396/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Vitamin D Supplementation on Cognitive Functions in Patients Receiving Maintenance Methadone Treatment

Public title
The effect of Vitamin D Supplementation on Cognitive Functions in Patients Receiving Maintenance Methadone

Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients that receiving methadone maintenance treatment Aged 18 to 60 years

Exclusion criteria:

Not living in Kashan Taking vitamin D, multivitamin-mineral, and antioxidant supplements during the last 3 months before the intervention.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

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

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

Ravand 5km Road، Medical science collection

City

Kashan

Province

Isfehan

Postal code

8814187159

Approval date

2017-02-28, 1395/12/10

Ethics committee reference number

IR.KAUMS.REC.1395.166

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to psychoactive substance use

Primary outcomes

1

Description

Risky Decision Making

Timepoint

At the baseline and after intervention (24 weeks)

Method of measurement

Iowa Gambling Task (IGT)

2

Description

Memory

Timepoint

At the baseline and after intervention (24 weeks)

Method of measurement

Wechsler Logic Memory

3

Description

Verba Fluency

Timepoint

At the baseline and after intervention (24 weeks)

Method of measurement

FAS task

4

Description

Speed Processing

Timepoint

At the baseline and after intervention (24 weeks)

Method of measurement

Digit Symbol and Trial Making Test (TMT)

Secondary outcomes

1

Description
Depression
Timepoint
At the baseline and after intervention (24 weeks)
Method of measurement
Beck Depression Inventory (BDI)

2

Description
Anxiety
Timepoint
At the baseline and after intervention (24 weeks)
Method of measurement
Beck Anxiety Inventory (BAI)

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
Intervention and control group: Methadone Maintenance Therapy (MMT)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golabchi Clinic
Full name of responsible person
Morad Rasouli-Azad
Street address
Shahid Rajaee Avenue
City
Kashan
Province
Isfehan
Postal code
8814187159
Phone
+98 31 5546 3378
Email
mrasoliazad@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard
City
Kashan
Province
Isfehan
Postal code
8814187159
Phone
+98 31 5554 2999
Email
hamiidi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, 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 Science
Full name of responsible person
Morad Rasouli-Azad
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Ravand 5km Road، Medical science collection
City
Kashan
Province
Isfehan
Postal code
8814187159
Phone
+98 31 5554 0021

Fax

Email

mrasoliazad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Science

Full name of responsible person

Morad Rasouli-Azad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Rvand 5Km road, Kashan Medical Science Collection

City

Kashan

Province

Isfehan

Postal code

8814187159

Phone

+98 31 5554 0021

Fax

Email

mrasoliazad@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Science

Full name of responsible person

Morad Rasouli-Azad

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Assistant professor

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8814187159

Phone

+98 31 5554 0021

Fax

Email

mrasoliazad@yahoo.com

Web page address

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