

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 placebo 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)

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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

Isfahan

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

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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

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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

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

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Person responsible for scientific inquiries

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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