

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessing the effect of vitamin D on the CD4 count and some blood indices in Human Immunodeficiency Virus (HIV) patients

Protocol summary

Study aim

Assessing the effect of vitamin D on the CD4 count and some blood indices in HIV patients

Design

Randomised with a parallel group design of 66 patients in intervention and control group by simple random sampling

Settings and conduct

The data collecting was performed at Varamin Behavioral Counseling Center. The information collecting method was conducted by interviewing and filling out the questionnaire. The last CD4 of these patients was measured during their periodic evaluation every 3 months. CBC tests were performed for all patients at the same time as their CD4 levels were measured. a Perl of 50,000 units of vitamin D3 was orally administered per month to patients in the intervention group. three and six months after the intervention, the questionnaire was again filled up for the complete research samples and the tests contained therein.

Participants/Inclusion and exclusion criteria

The inclusion criteria are include non-pregnant women and men who had HIV infection, age older than 18 years, intervals of at least 6 months since the start of the last regimen, not taking vitamin supplements at least three months before the start of the study, no diseases and acute problems preventing intervention by taking vitamin D3 Exclusion criteria are include modifying the antiretroviral therapy during the study, getting pregnancy in female patients, the absence of referral patients for monthly supplementation of vitamin D3, people with sarcoidosis, hyperparathyroidism, kidney disease and histoplasmosis

Intervention groups

Intervention group: People who in addition to receiving antiretroviral drug take a Perl of 50,000 units of vitamin D3 orally per month. control group: People who only receive antiretroviral drug.

Main outcome variables

Increased levels of vitamin D3 in patients: Increased number of CD4 and other blood factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180926041146N1**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **retrospective**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Zohreh Haghighatdana

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3624 2937

Email address

haghighatz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-20, 1395/03/31

Expected recruitment end date

2018-03-05, 1396/12/14

Actual recruitment start date

2016-06-20, 1395/03/31

Actual recruitment end date

2018-03-05, 1396/12/14

Trial completion date

2018-09-05, 1397/06/14

Scientific title

Assessing the effect of vitamin D on the CD4 count and some blood indices in Human Immunodeficiency Virus (HIV) patients

Public title

Effect of vitamin D on maintaining immunity level in HIV patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age older than 18 years Non-pregnant women Intervals of at least 6 months since the start of the last regimen Not taking vitamin supplements at least three months before the start of the study No diseases and acute problems preventing intervention by taking vitamin D3 Lack of psychological illnesses and willingness to cooperate in this research project

Exclusion criteria:

Modifying the antiretroviral therapy during the study Getting pregnancy in female patients The absence of referral patients for monthly supplementation of vitamin D3 even for one month The occurrence of any illness or specific problem during the conduct of the research People with sarcoidosis, hyperparathyroidism, kidney disease and histoplasmosis

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, by simple random sampling, the names of all people met the inclusion criteria were listed in the list of registered individuals at the specialist offices of the counseling center. After examining their files, their phone numbers and addresses were extracted. They were contacted and if they were enrolled to the study, if they were willing to cooperate and participate. Individuals were randomly entered the intervention and control groups. In this way, the cards with numbers 1 and 2 were prepared; the code of one was related to intervention as compared to the code of two for control group. These cards were placed in a thick envelope, and patients in the first stage of sampling, when they went to each, chose a card, and they were placed in the corresponding group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Erabi Ave., Yeman Blvd., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-08-13, 1397/05/22

Ethics committee reference number

IR.SBMU.PHNS.REC.1397.36

Health conditions studied**1****Description of health condition studied**

HIV

ICD-10 code

B23.2

ICD-10 code description

HIV disease resulting in haematological and immunological abnormalities, not elsewhere classified

Primary outcomes**1****Description**

CD4 Cells Count

Timepoint

Before intervention, three and six months after intervention

Method of measurement

Blood Test

Secondary outcomes**1****Description**

Complete Blood Count
Timepoint
Before intervention, three and six months after the intervention
Method of measurement
Blood Test

Intervention groups

1

Description

Intervention group: A Perl of 50,000 units of vitamin D3 was orally administered per month. Then, three and six months after the intervention, the questionnaire was again filled up for the complete research samples and the tests contained therein.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Varamin Behavioral Counseling Center
Full name of responsible person
Zohreh Haghighatdana
Street address
Shahid Beheshti Ave.
City
Varamin
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3371664339
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Haghighatz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Hossein Hatami
Street address
Next to Ayatollah Taleghani Hospital, Shahid Erabi Ave., Yeman Blvd., Shahid Chamran Highway
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Tehran
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Postal code

1985717443

Phone

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Email

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zohreh Haghighatdana
Position
MPH, MSc Midwifery
Latest degree
Master
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zohreh Haghighatdana

Position

MPH, MSc Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available