

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of Selenium supplementation on CD4+ T lymphocyte count in HIV+ patients referred to Iranian HIV/AIDS Research Center (IRCHA)

Protocol summary

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Summary

The objective of this randomized double blind trial is to investigate the effect of Selenium supplementation on the CD4+ lymphocyte cell count in HIV infected patients. In this study, 100 HIV Infected patients who meet eligibility criteria will be randomly assigned into intervention or control group. The patients in the intervention group will receive Selenium gluconate capsule, 200 µgr elemental, daily for 6 months but in the control group will receive placebo. CD4+ lymphocyte cell count, blood hemoglobin level, body mass index, rate of opportunistic infections, and serum level of Selenium will be measured and compared between groups.

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-06-20, 1390/03/30

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904244380N2**

Registration date: **2010-07-15, 1389/04/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-07-15, 1389/04/24

Registrant information

Name

Azar Haddadi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

Scientific title

Determining the effect of Selenium supplementation on CD4+ T lymphocyte count in HIV+ patients referred to Iranian HIV/AIDS Research Center (IRCHA)

Public title

Determining the effect of Selenium supplementation on CD4+ T lymphocyte count in HIV+ patients referred to Iranian HIV/AIDS Research Center (IRCHA)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age 18-60 years, Confirmed HIV-1 infection with western blot test, receiving HAART, CD4 between 200 and 350, signing informed consent
Exclusion criteria: Pregnancy, any other supplementation than Selenium, history of hypersensitivity to Selenium, unwilling to cooperate, any plan to leave Tehran during the next 9 months after beginning of the study, History of chronic kidney diseases

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee Of Tehran University of Medical Sciences and Health Services

Street address

Medical Ethics Building, 16th Azar avenue, Tehran,

City

Tehran

Postal code**Approval date**

empty

Ethics committee reference number

404 /130 /89/ص

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

HIV infection

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

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

CD4+ T cell count

Timepoint

Baseline, every 3 months up to the end of the study

Method of measurement

flowcytometry

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

serum Selenium level

Timepoint

Baseline and at the end of the study

Method of measurement

Atomic absorption spectrometry

2**Description**

Body mass index

Timepoint

Baseline and at the end of the study

Method of measurement $\text{weight(kg)/height(m)} \times \text{height(m)}$ **3****Description**

Blood hemoglobin

Timepoint

Baseline and at the end of the study

Method of measurement

CBC test

4**Description**

Rate of opportunistic infections

Timepoint

Every month during the study

Method of measurement

Medical history and physical examination

Intervention groups**1****Description**

Selenium gluconate 200 µgr elemental capsule once daily for 6 months

Category

Treatment - Drugs

2**Description**

Placebo capsule, with the same taste and color and size, once daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian HIV/AIDS Research Center (IRCHA)

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences,

City

Tehran

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, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahar yousefi

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Infectious disease Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty