Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

The effect of zinc supplementation on CD4+ lymphocyte cell count in HIV patients in Iranian research center: a randomized double blind controlled trial

Protocol summary

Summary

The objective of this randomized double blind trial is to investigate the effect of Zinc 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 Zinc sulfate, 220 mg capsule (50 mg elemental zinc), 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 zinc will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904244380N1**
Registration date: **2011-06-20, 1390/03/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-20, 1390/03/30

Registrant information

Name

Azar Haddadi

Name of organization / entity

Tehran University of Medical Sciences

Country

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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

Scientific title

The effect of zinc supplementation on CD4+ lymphocyte cell count in HIV patients in Iranian research center: a randomized double blind controlled trial

Public title

The effect of zinc supplementation on CD4+ lymphocyte cell count in HIV patients in Iranian research center: a randomized double blind controlled trial

Purpose

Treatment

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 zinc, history of hypersensitivity to Zinc, 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
0
Groups that have been masked
No information
Sample size
Target 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
Street address
Medical Ethics Building, 16th Azar avenue, Tehran,
City
Tehran
Postal code
Approval date
2010-06-10, 1389/03/20
Ethics committee reference number
130/403/89/ص

Health conditions studied

1

Description of health condition studied
HIV infection
ICD-10 code
B24
ICD-10 code description
Unspecifidied immunodeficiency virus [hiv]disease

Primary outcomes

1

Description
CD4+ lymphocyte cell count
Timepoint
Baseline, every 3 months up to the end of the study
Method of measurement
Flowcytometry

Secondary outcomes

1

Description
Body mass index
Timepoint
Baseline and at the end of the study
Method of measurement
weight(kg)/height(m)×height(m)

2

Description
Blood hemoglobin
Timepoint
Baseline and at the end of the study
Method of measurement
CBC TEST

3

Description
Rate of opportunistic infections
Timepoint
Every month during the study
Method of measurement
Medical history and physical examination

4

Description
Serum level of zinc
Timepoint
Baseline and at the end of the study
Method of measurement
atomic absorption spectrometry

Intervention groups

1

Description
Control group: Placebo capsule (the same in taste and colour to zinc capsule) once daily during 6 months study intrvention
Category
Placebo

2

Description
Intevention group: Zinc sulphate 220 mg capsule contains 50 mg elemental zinc once daily during 6 months study
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian AIDS Reasearch center
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 Fotuhi
Street address
Tehran University of Medical Sciences, Tehran, Iran
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
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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