

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 21 6671 6546

##### Email address

haddadiaz@tums.ac.ir

##### 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) $\times$ 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**

Intervention 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 Research 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**

Tehran university of medical science, medical school

**Full name of responsible person**

Behnaz Edalatnoor

**Position**

Medical Student

**Other areas of specialty/work**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Tehran university of medical science, medical school

**Full name of responsible person**

Dr Azar Haddadi

**Position**

Infectious diseases Associate Professor

**Other areas of specialty/work**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Behnaz Edalatnoor

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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*