

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Randomized placebo controlled trial of cyproheptadine for prevention of neuropsychiatric adverse effects of antiretroviral including efavirenz.

Protocol summary

Summary

The aim of this placebo controlled double blind randomized clinical trial will be to assess the efficacy of cyproheptadine for prevention of neuropsychiatric effects of EFV. Inclusion criteria are patients with HIV-1 infection older than 18 years who are scheduled to receive an efavirenz-containing treatment. The main exclusion criteria are previous treatment with antiretroviral drugs including efavirenz, having major psychiatric disorders like depression at the beginning of this study. A total of 50 patients will be recruited from Emam Khomeiny hospital clinic. These patients will be divided in to two groups (intervention and placebo), each have 25 patients, using block randomization. After signing informed consent form by patients, cyproheptadine will be administered 8 mg per day for one week and 12 mg per day for other 3 weeks in interventional group and patients will take placebo with the same dose and frequency in control group. The patients will be followed for 4 weeks. Neuropsychiatric effects will be evaluated with followed scales on day 0 and 28 after treatment, Hamilton depression and anxiety, beck depression, Pittsburgh Sleep Quality, suicidal thoughts, Symptom Checklist 90, Positive and Negative Syndrome Scale will be assessed and compared in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103106026N1**
Registration date: **2011-05-01, 1390/02/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-05-01, 1390/02/11

Registrant information

Name

Fatemeh Dabaghzadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-09-24, 1391/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized placebo controlled trial of cyproheptadine for prevention of neuropsychiatric adverse effects of antiretroviral including efavirenz.

Public title

Cyproheptadine for prevention of neuropsychiatric adverse effects of antiretrovirals including efavirenz

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with HIV-1 infection, older than 18 years who are scheduled to receive an efavirenz-containing treatment Exclusion criteria: Previous treatment with antiretroviral drugs including efavirenz,

pregnancy, use of other medications that be effective on patient's mood such as methadone and having major psychiatric disorders like depression at the beginning of this study.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Tehran University of Medical Sciences and Health Services

Street address

Tehran University of Medical Sciences and Health Services, Enghelab ave, Tehran, Iran

City

Tehran

Postal code**Approval date**

2011-01-18, 1389/10/28

Ethics committee reference number

89-04-33-11884

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

Human immunodeficiency virus [HIV] disease

ICD-10 code

B23

ICD-10 code description

Human immunodeficiency virus [HIV] disease resulting in other conditions

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

Neuropsychiatric effects of efavirenz

Timepoint

Before intevention, 4 weeks after intervention

Method of measurement

Questionnaire

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

Appetite

Timepoint

Before intevention, 4 weeks after intervention

Method of measurement

Questionnaire

2**Description**

Weight

Timepoint

Before intevention, 4 weeks after intervention

Method of measurement

Weight scale

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

Interventional group: cyproheptadine, oral tablet 4 mg, 2 tablets at night for 1 week.cyproheptadine, oral tablet 4 mg, 3 tablets at night for other 3 weeks

Category

Treatment - Drugs

2**Description**

Control group: cyproheptadine placebo, oral tablet 4 mg, 2 tablets at night for 1 week.cyproheptadine placebo, oral tablet 4 mg, 3 tablets at night for other 3 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Dr.Hossein Khalili

Street address

Tehran, Imam Khomeini hospital, Infection ward

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor for Research, Tehran University of
Medical Sciences and Health Services

Full name of responsible person
Dr. Akbar Fotouhi

Street address
Tehran University of Medical Sciences and Health
Services, Enghelab Ave, 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 and Health Services

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Department of Clinical Pharmacy, Faculty of
Pharmacy, Tehran University of Medical Sciences and
Heal

Full name of responsible person
Hossein Khalili

Position
Phrm.D, BCPS, Associate Professor

Other areas of specialty/work

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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