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 pervious 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
Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5034
Email address
dabaghzadeh@razi.tums.ac.ir

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: Pervious 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
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences and Health Services, Enghelab Ave, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 6695 4715
Fax
Email
khalilih@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Fatemeh Dabaghzadeh
Position
Pharm.D, Resident of clinical pharmacy
Other areas of specialty/work
Street address
Tehran University of Medical Sciences and Health Services, Enghelab Ave, Tehran, Iran
City
Tehran
Postal code
1417614411
Phone
+98 21 6695 4715
Fax
Email
fatemeh_dabaghzadeh@yahoo.com
Web page address

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