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 into 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

Country
Iran (Islamic Republic of)
Phone
+98 34 3132 5034
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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 antiretrovirals 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 intervention, 4 weeks after intervention
Method of measurement

Secondary outcomes

1
Description
Appetite
Timepoint
Before intervention, 4 weeks after intervention
Method of measurement
Questionnaire

2
Description
Weight
Timepoint
Before intervention, 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
empty

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 Health

Full name of responsible person
Hossein Khalili

Position
Phrm.D, BCPS, Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Pharm.D, Resident of clinical pharmacy

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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