Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing efficacy and safety of Valerian and Placebo for prevention of Efavirenz-induced anxiety and depression in HIV positive patients

Protocol summary

Summary

Aim of the study: Evaluation of efficacy and safety of Valerian for prevention of neuropsychiatric adverse effects of Efavirenz in HIV positive patients. Design: A Randomized Placebo Controlled Clinical Trial Patients: 50 patients with confirmed HIV infection, aged 18-65 years old who are candidate for antiretroviral therapy with Efavirenz will be included. Pregnant and lactating women, patients with positive history of neuropyschiatric disorders and who are receiving mood affecting agents will be excluded. Included patients will be assigned to drug or placebo group based on the block randomization method. Patients in the drug group will be receive 2 capsules of Sedamin (530 mg of dry extract of Valerian root- GolDaru Pharmaceutical Company- Isfahan-IRAN), 2 hours before bed time for 4 weeks. Patients in the placebo group will be receive 2 capsules of Placebo (GolDaru Pharmaceutical Company- Isfahan-IRAN), 2 hours before bed time for 4 weeks. Assessment: Patients will be followed up in term of the neuropsychiatric adverse effects of Efavirenz (depression, anxiety, sleep disturbance, positive and negative suicide ideation, psychotic symptoms) based on the Hamilton Anxiety and Depression, Pittsburgh Sleep Quality, Positive and Negative Suicide Ideation and Negative and Positive Symptoms of Psychosis questionnaires at times 0 and week 4. Also adverse effects of the Valerian will be evaluated in the patients during the study period. At end of the study efficacy and safety of Valerian in prevention of neuropsychiatrics adverse effects of Efavirenz will be compared with placebo.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504053449N18**
Registration date: **2015-12-06, 1394/09/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-12-06, 1394/09/15

Registrant information

Name
Hossein Khalili
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of Valerian and Placebo for prevention of Efavirenz-induced anxiety and depression in HIV positive patients

Public title

Valerian for prevention of neuropsychiatric adverse effects of Efavirenz in HIV positive patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with confirmed HIV infection, between 18-65 years old, receiving Efavirenz containing antiretroviral treatment. Exclusion criteria: Pregnant and lactating women, previous treatment with Efavirenz, positive history of neuropyschiatric disorders such as severe depression, patients who are receiving mood affecting agents (such as Methadone), positive history of hypersensitivity to herbal products including Valerian, discontinuation of antiretroviral therapy by patient due to any reason, patients who do not tolerate side effects of Valerian (headache, vertigo, stomach pain, nausea, vomiting, diarrhea and palpitation).

Age

From **18 years** old to **65 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

Included patients will be assigned to the Valerian or placebo group based on the block randomization method. Randomization and distribution of the Valerian or placebo will be done by the hospital pharmacy department and researchers, physicians and patients will be blinded regarding type of intervention (Valerian or placebo).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods Ave.

City

Tehran

Postal code

Approval date

2015-11-25, 1394/09/04

Ethics committee reference number

IR.TUMS.REC.1394.1280

Health conditions studied

1

Description of health condition studied

Neuropsychiatric disorders

ICD-10 code

F10-19.5

ICD-10 code description

A cluster of psychotic phenomena that occur during or following drug use

Primary outcomes

1

Description

Depression, Anxiety, Sleep Disturbance. Positive and Negative Suicide Ideation, Positive and Negative Symptoms of Psychosis

Timepoint

At baseline and 4 weeks later

Method of measurement

The Hamilton Depression and Anxiety, Pittsburgh Sleep Quality, Positive and Negative Suicide Ideation, Positive and Negative Symptoms of Psychosis Scales

Secondary outcomes

1

Description

Safety of Valerian

Timepoint

During the study

Method of measurement

Patients reports and follow up

Intervention groups

1

Description

2 capsules of Sedamin (530 mg of dry extract of Valerian root- GolDaru Pharmaceutical Company- Isfahan-IRAN) every night 2 hours before bed time for 4 weeks.

Category

Treatment - Drugs

2

Description

2 Capsules of Placebo (GolDaru Pharmaceutical Company- Isfahan-IRAN) every night 2 hours before bed time for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hossein Khalili
Street address
Keshavarz Blvd.
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
Masoud Yunesian
Street address
Ghods Ave.
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
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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