# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Jan 2020

## 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
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 6695 4715
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khalilih@tums.ac.ir

**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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Pharm. D
**Other areas of specialty/work**
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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*