

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effectiveness of endocrine disorders therapy in depression improvement of HIV infected men referring to counseling center at Imam Khomeini hospital in 92

Protocol summary

Summary

1) Objective: Evaluation of effectiveness of endocrine disorders therapy in depression improvement of HIV infected men. 2) Design: This study is Interventional on HIV positive patients in whom Beck score is more than 21 with hormonal treatment. 3) Setting and conduct: 104 HIV infected men in counseling center of Imam Khomeini hospital in whom Beck score is more than 21 will be selected and endocrine tests will be done for them. The patients with endocrine disorders confirmed by lab tests, will be treated with hormonal medications and reevaluation of depression with Beck questionnaire will be done in the end of treatment. 4) Major eligibility criteria: Inclusion criteria: HIV+ confirmed by Western Blot; Patient on ART treatment; Beck questionnaire with score > 21. Exclusion criteria: Consumption of antidepressant drugs; Confirmed endocrine disorder; Any sign of infectious disease such as fever; Opportunistic infections; addiction; Major depression with suicidal attempt or emotional events in last month. 5) Intervention: Hormonal medications in depressed patients. 6) main outcome measures variables: Depression with Beck questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071914054N1**
Registration date: **2013-12-25, 1392/10/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-25, 1392/10/04

Registrant information

Name

Ladan Abbasian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1598

Email address

la-abbasian@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-12-01, 1393/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of endocrine disorders therapy in depression improvement of HIV infected men referring to counseling center at Imam Khomeini hospital in 92

Public title

The effectiveness of endocrine disorders therapy in depression improvement of HIV infected men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: HIV+ confirmed by Western Blot;
Patient on ART treatment; beck questionnaire with score>21
Exclusion criteria: Consumption of antidepressant drugs;
Confirmed endocrine disorder ;
Any sign of infectious disease such as fever;
Opportunistic infections; addiction; Major depression with suicidal attempt or emotional events in last month.

Age

From **18 years** old to **80 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Tehran University of Medical Sciences

Street address

Keshavarz Blvd, Ghods St

City

Tehran

Postal code

Approval date

2013-07-15, 1392/04/24

Ethics committee reference number

92-01-30-21556-89225

Health conditions studied

1

Description of health condition studied

HIV infected people

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Depression

Timepoint

Detection of depression before and after intervention

Method of measurement

Beck questionnaire

Secondary outcomes

1

Description

Endocrine lab tests: TSH,T3RU,T4,T3,ACTH,UFC, plasmacortisol ,PRL,LH,FSH, freeTestosterone

Timepoint

Before and after intervention

Method of measurement

Laboratory tests

Intervention groups

1

Description

For treatment if we will have hypogonadism testosterone 250 unit monthly will given,in cases of hypothyroidism levothyroxine 100 macro gram daily and in cases of hyperthyroidism methimazole 15 mg daily for 3 weeks and then 10 mg daily will prescribed.For hypocortisolism as a 20 mg hydrocortisone will given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

HIV Clinic

Full name of responsible person

Ladan Abbasian

Street address

Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Hajar Moamail

Street address
Keshavarz Blvd, Qods street

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 of 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

Name of organization / entity
Iranian research center for HIV/ AIDS

Full name of responsible person
Fereshte Ghasvand

Position
Infectious Diseases Resident

Other areas of specialty/work

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Imam Khomeini Hospital, Keshavarz Blvd

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Person responsible for scientific inquiries

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Position
MD, MPH, Infectious Disease Specialist

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Person responsible for updating data

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Full name of responsible person
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Position
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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