Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of green tea consumption in the treatment of mild to moderate depression in HIV patients. A randomized, double-blind, controlled clinical trial

Protocol summary

Summary

(1) Objective: The effect of green tea consumption on the treatment of mild to moderate depression in patients with HIV compared with placebo who are being treated with highly active antiretroviral therapy.(2) Design: Randomized, double blind, controlled clinical trials, single center, phase II prospective clinical trial in Fifty HIV-infected patients. (3) Setting and conduct: Patients referred to Imam Khomeini Hospital Counseling Center during 1396 to 1397 are randomly allocated to the intervention and placebo groups.(4) Participants: Main inclusion criteria are confirmation of HIV infection based on the Western Blot test; diagnosing mild to moderate of depression and have a Hamilton test score of under 20; lack of other psychiatric and cognitive diseases; Major exclusion criteria: Opportunistic infection during 90 days before entering the study; Severe depression and suicidal tendency based on the Hamilton suicide rate score ≥2; have cancer and pregnancy or delivery in three months ago, or breastfeeding; consuming tea and herbal products for 1 week before baseline evaluation and during the study period. (5) Intervention: The intervention group takes every 12 hours of the Green tea capsule (400 mg polyphenol) and the placebo group takes placebo capsule every 12 hours, for 3 months. (6) Main outcome measures: Hamilton score is measured at weeks 6 and 12 and side effects are measured at weeks 1, 6 and 12 in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071128308N2**
Registration date: **2017-10-14, 1396/07/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-10-14, 1396/07/22

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of green tea consumption in the treatment of mild to moderate depression in HIV patients. A randomized, double-blind, controlled clinical trial

Public title

The effect of green tea on the treatment of depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : confirmation of HIV infection based on Western blot test; receiving highly active antiretrovirals; diagnosing mild to moderate of depression based on DSM IV criteria (Diagnostic and Statistical Manual of mental disorders) and have a Hamilton test (17 items) score of under 20; satisfaction for research; lack of other psychiatric and cognitive diseases (including AIDS-induced dementia). Exclusion criteria: opportunistic infection 90 days before entering the study; severe depression, and a tendency to suicide based on the Hamilton suicide rate, ≥2; have cancer and pregnancy or delivery in three months ago, or breastfeeding; alcohol dependency; people with malabsorption disorder such as Crohn's disease or chronic pancreatitis; the intake of proton pump inhibitor or H2 blocker; the inability to refrain from drinking tea / tea products (including herbal, caffeine free, caffeine free, Apple juice, chocolate, bean, cherry, juice containing apple, cherry, or plum, food supplements, and herbs for 1 week before baseline evaluation and during the study period.

Age

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

Gender

Both

Phase

2

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

Randomization is done by Permuted-4th block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of medicine

City

Tehran

Postal code

Approval date

2017-09-25, 1396/07/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3572

Health conditions studied

1

Description of health condition studied

HIV

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, 6 weeks after the intervention and 12 weeks after intervention

Method of measurement

Hamilton Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

A green tea capsule containing 400 mg of green tea polyphenols (GTP) every 12 hours for 12 weeks

Category

Treatment - Drugs

2

Description

A placebo capsule every 12 hours for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Behavioral health counseling center, Imam Khomeini.

Full name of responsible person

Dr. Mousavi

Street address
Imam Khomeini Hospital, End of 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
Dr. Masoud Younesian
Street address
Tehran University of Medical Sciences Headquarters, Keshavarz Blvd., First of Ghods St.,
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
Name of organization / entity
Tehran University of Medical Science
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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