

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The evaluation of effect of herbal supplement (Melissa Officinalis and Hypericum perforatum along with DDW water) on the improvement of clinical symptoms, CD4 level and the viral load of HIV positive patients: A randomized double blind clinical trial study

Protocol summary

Study aim

To study the effectiveness of HMD 99 capsules formulated with Hypericum p. and Melissa o. extract with deuterium depleted water, on improving the clinical signs, CD4 level and viral load in HIV infected patients

Design

Phase 3 clinical study with 100 patients, double blind and randomized according to a randomized table, with a control group (placebo) and a treatment group (HMD 99 capsules).

Settings and conduct

After patient selection according to guidelines the study will continue 90 days at the Imam Khomeini hospital in Tehran. Participation in the study is voluntary meaning the patients must volunteer to participate. The assessment of the effectiveness and side effects of the drug will be determined by comparing the results between the control and the treated groups.

Participants/Inclusion and exclusion criteria

Written knowing and voluntary consent, patient age between 18 to 65, patients must have two positive ELISA HIV tests, patients who have failed to benefit from anti-retroviral medication due to drug resistance. Excluded: patients whose blood viral level can not be measured (undetectable), patients with Hepatitis B or C, pregnancy and lactation, patients using immune enhancers within 6 months, current use of drugs or alcohol, use of growth hormone testosterone or anabolic steroids within 30 days prior to entering study, long-term use of immunosuppressants (except for topical steroids); chemotherapy, interferon treatment or radiotherapy (3 weeks prior to entering study)

Intervention groups

Experimental group: will receive 3 capsules per day, containing 400 mg formulation of Hypericum p. and Melissa o. extract prepared with deuterium depleted

water, for 90 days. Control group: will receive and use 3 capsules per day containing placebo for 90 days.

Main outcome variables

Laboratory parameters: HIVAb , CBC , ,ALK AST/ALT , BUN , Cr , FBS , Viral load, CD4 level.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050373N3**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Seyed ahmad Seyed alinaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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s_a_alinaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of herbal supplement (Melissa Officinalis and Hypericum perforatum along with DDW water) on the improvement of clinical symptoms, CD4 level and the viral load of HIV positive patients: A randomized double blind clinical trial study

Public title

The evaluation of effect of herbal supplement (Melissa Officinalis and Hypericum perforatum along with DDW water) on the improvement of clinical symptoms, CD4 level and the viral load of HIV positive patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients must give their knowing and voluntary written consent to join the study Patients must have at least two positive ELISA HIV test results Patients who have failed to benefit from anti-retroviral drugs due to drug resistance

Exclusion criteria:

Patients with undetectable levels of blood viral content Patients with Hepatitis B or C Pregnancy and lactation Patients who have used immuno-enhancers; use of antibiotics and other prescribed medication to treat AIDS symptomology is excepted Present use of illegal drugs or alcohol Use of growth hormone 30 days prior to the study Use of testosterone or anabolic steroids 30 days prior to the study Chemotherapy, radiotherapy or interferon treatment 3 weeks prior to entering the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A table of randomized numbers (with a number for each patient) shall be used for randomization of treatment in the study. In this table, half the numbers are coded for HMD 99 capsule and the other half for placebo without the administrators prior knowledge. Prescription of HMD 99 capsule or placebo for each patient shall be done by picking numbers from the table and matching them to the code for the medication or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is double-blind study in which neither the patients nor the medical care staff/physicians will have information regarding treatment (capsule or placebo) each patient is receiving. The double-blind set up of the study will use coded packages for capsules and placebo which look identical

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research Imam Khomeini Hospital Complex, Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Keshavarz Blvd., Dr. Gharib Street

City

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Province

Tehran

Postal code

1419733141

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.410

Health conditions studied**1****Description of health condition studied**

AIDS

ICD-10 code

042

ICD-10 code description

Human immunodeficiency virus (HIV) disease

Primary outcomes**1****Description**

HIVAb

Timepoint

AT the beginning and the ending of the study

Method of measurement

HIVAb ELISA

2

Description

CBC

Timepoint

At the beginning and the ending of the study

Method of measurement

Blood Test

3

Description

Viral Load

Timepoint

Beginning and the ending of the study

Method of measurement

PCR

Secondary outcomes

1

Description

AIDS-related clinical signs and drug interactions

Timepoint

Weekly during the course of the study

Method of measurement

Physician's examinations and phone calls in case of occurrence of signs and symptoms

Intervention groups

1

Description

Intervention group: This group shall receive 3 HMD 99 capsules per day, each containing 400 mg of Hypericum p. and Melissa o. formulation prepared with deuterium depleted water, for 90 days.

Category

Treatment - Drugs

2

Description

Control group: This group shall receive and take 3 placebo capsules (containing commonly used excipients in pharmaceuticals for producing placebo) for 90 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling Center for Behavioral Disorders, Imam Khomeini Hospital

Full name of responsible person

Doctor Seyed Ahmad Seyed Alinaghi, Physician

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Imam Khomeini Hospital Complex, Keshavarz Blvd., Dr. Gharib Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

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Email

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor of Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital, Tehran

Full name of responsible person

Seyed Ahmad Seyed Alinaghi, M.D.

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available