Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)

Phone
+98 21 6658 1583

Email address
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
Tehran
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 sings 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
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Dr. Gharib Street
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir

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
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Dr. Gharib Street
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir
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
Epidemiology
Street address
End of Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1583
Email
a_alinaghi@sina.tums.ac.ir

Person responsible for scientific 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
Epidemiology
Street address
End of Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6658 1583
Email
a_alinaghi@sina.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
PNU University, Tehran
Full name of responsible person
Mehran Zamany
Position
Ms. Sc. Biochemistry, student
Latest degree
Bachelor
Other areas of specialty/work
Biochemistry
Street address
Shahid Mohabadipour St., #52
City
Tehran
Province
Tehran
Postal code
1675614543
Phone
+98 21 2251 0710
Email
ronniezamany7@gmail.com

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