Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

"Examining the Effectiveness and Side Effects of Softgel-Encapsulated IMOD in Individuals Living with HIV"

Protocol summary

Study aim
Examining the effectiveness of oral medication IMOD in improving immunological and virological indices in HIV-positive patients

Design
A randomized, controlled clinical trial, with parallel groups, phase 3, on 120 patients, double-blind. Randomization will be done using the block method.

Settings and conduct
Patients with positive HIV who visit the infectious diseases department of Imam Khomeini Hospital in Tehran, will be divided into two groups. One group will receive intervention treatment with oral medication IMOD in the form of a gel, equivalent to 120 milligrams of pure extract, along with antiretroviral therapy. The other group will be the control group and receive treatment with antiretroviral drugs. Patients in both groups will undergo treatment for a period of 3 months. Participation in this project is voluntary, meaning that patients must volunteer themselves to participate. To better evaluate the therapeutic effects and side effects of this medication, patients in the intervention group will be assessed before and after the treatment, and the results of the intervention and control groups will be compared.

Participants/Inclusion and exclusion criteria
6Inclusion criteria: Written informed consent; Age between 18 and 65 years; Positive results for two HIV ELISA tests and one Western blot test. Exclusion criteria: Patients with hepatitis B or C; Pregnancy and lactation; Current substance abuse or alcohol consumption; Use of growth hormone within 30 days before study entry; Using testosterone or anabolic steroids (30 days before entering the study); long-term treatment with immunosuppressive drugs (except topical steroids); Chemotherapy, interferon treatment or radiotherapy (three weeks before entering the study).

Intervention groups
Intervention group: oral medication IMOD in the form of a gel. Control group: receiving treatment with antiretroviral drugs.

Main outcome variables
CBC; ALK phos; AST/ALT; BUN; Cr; FBS; Viral load; CD4 count; Drug side effects.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180610040037N5**
Registration date: **2023-07-17, 1402/04/26**
Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**
Update count: **0**

Registration date
2023-07-17, 1402/04/26

Registrant information

Name
Seyed Ali Dehghan maneshadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"Examining the Effectiveness and Side Effects of Softgel-Encapsulated IMOD in Individuals Living with HIV"

Public title
A Study on the Efficacy and Side Effects of Softgel-Encapsulated IMOD in Individuals with HIV"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having written informed and voluntary consent. The patient's age should be between 18 and 65 years. The patient should have two positive HIV ELISA tests and one positive Western blot test.
Exclusion criteria:
The patient has hepatitis B or C. Pregnancy or breastfeeding. Current use of illicit drugs or alcohol. Use of growth hormone (within 30 days prior to study entry). Use of testosterone or anabolic steroids (within 30 days prior to study entry). Long-term treatment with immunosuppressive drugs (except for topical steroids). Chemotherapy, interferon therapy, or radiotherapy (within three weeks prior to study entry).
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: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, randomization and allocation of patients into intervention and control groups are performed using a random block design. This method involves using a table of random blocks, where each block has an equal size, and within each block, random allocation of patients to the groups takes place. The steps for implementing randomization using a random block design are as follows: Determine the block size: In this step, the number of patients to be included in each block is determined. For example, if we want each block to consist of 4 patients, the block size would be 4. Create the blocks: Based on the total number of patients (in this case, 120 patients), the necessary blocks for allocating patients to the groups are created. For example, if we consider the total number of patients as 120 and each block to have 4 patients, then 30 blocks will be created. Randomly allocate patients: Within each block, patients are randomly allocated to the intervention and control groups. For this purpose, simple randomization methods such as using a random number table, computational software, or other randomization techniques are employed. By conducting this random allocation, each patient will have an equal chance of being assigned to either group, ensuring the balance and randomness of patient allocation. Therefore, the random block design provides a straightforward approach to achieve randomization and allocation of patients in a controlled manner, enhancing the validity and reliability of the study results.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients were allocated to the two groups through the block randomization table, but neither the person responsible for drug administration nor the patients themselves were aware of which group received the IMOD medication and which group received the placebo. This information was kept completely concealed from them. To maintain blinding, the drugs were designed to have similar shapes and colors, as coordinated, so that patients and the person responsible for drug administration would not be able to distinguish between the IMOD medication and the placebo. Throughout the study period, all patients were examined and assessed for clinical symptoms related to HIV and drug-related side effects. These evaluations aimed to identify and record drug-related adverse events and clinical symptoms associated with the disease in both groups. This approach ensured the preservation of double-blindness in the study and the unbiased nature of the results, independent of the knowledge and diagnosis of the individuals and patients."
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences.
Street address
Tehran, Keshavarz Boulevard, Corner of Qods Street, Central Organization of Tehran University of Medical Sciences.
City
Tehran.
Province
Tehran
Postal code
1417653761
Approval date

2023-06-12, 1402/03/22

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.097

Health conditions studied

1

Description of health condition studied

+HIV

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description

CD4 count: The number of CD4 lymphocytes in the blood.

Timepoint

3 months

Method of measurement

Laboratory report

2

Description

Laboratory indices of patients : Complete blood cell count/ Alkaline phosphatase level in the blood, measured to assess liver function/ Liver enzymes level in the blood /Blood urea nitrogen (BUN) level, measured to assess kidney function /Blood creatinine level, measured to assess kidney function /Fasting blood glucose level .

Timepoint

3 months

Method of measurement

Laboratory report

3

Description

Acute and chronic side effects of oral medication IMOD: Any type of drug-related adverse event based on the physician's diagnosis .

Timepoint

3 months

Method of measurement

Clinical symptoms and physical examination.

4

Description

Viral load: The number of viruses in the blood.

Timepoint

3 months

Method of measurement

Laboratory report

Secondary outcomes

empty

Intervention groups

1

Description

Oral IMOD medication and antiretroviral therapy: The intervention group consists of 60 individuals who will receive treatment with oral IMOD medication containing a combination of Tanacetum vulgare, Rosa canina, and Urtica dioica extracts. The medication is manufactured by Zist- Arvand Pharmed Factory and is formulated in the form of a soft gel equivalent to 120 mg of pure extract. They will undergo antiretroviral therapy for a duration of 3 months.

Category

Treatment - Drugs

2

Description

Control group will receive antiretroviral drugs based on the treatment regimens recommended by the guidelines in Iran for a duration of 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling centers for behavioral disorders in Tehran.

Full name of responsible person

Dr. Seyed Ali Dehghan Maneshadi

Street address

Imam Khomeini Hospital in Tehran, located at the end of Keshavarz Boulevard.

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a_dehghanm@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Fotouhi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Dehghan-Maneshadi
Position
Assistant Professor
Latest degree
Specialist
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)
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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available