Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Adjuvant IMOD therapy on the Immunological Status of HIV-positive Patients: A Random Controlled Clinical Trial

Protocol summary

Summary

Objectives : Determining the effects of adding the Iranian medicine IMOD to HAART regimen on the immunological condition of HIV+ patients Design: In this random controlled clinical trial, after explaining the study to the patients and obtaining written consent from them, 60 HIV+ patients for whom HAART was indicated were divided into the two identical groups: the control, who received only HAART, and the intervention group, who received infusion of IMOD in addition to HAART. Randomization was carried out through using simple random sampling. Setting and conduct : The HAART regimen used in this study for patients in both groups included NNRTI + 2NRTI. IMOD was in 120 mg vials in 4 cc, which was diluted in 50-100 cc of 5% dextrose and injected intravenously in half an hour. Patients received one ampoule (vial) of IMOD daily for a maximum period of 90 days. Observation, examination, equipment, and laboratory information were the information collecting tools in this research. Participants including : HIV+ patients (with two positive ELIISA tests and one positive Southern blot analysis) for whom HAART was indicated Interventions: Intravenous administration of IMOD Main outcome measures : Before and after the treatment, BUN, Cr, total lymphocyte count (TLC), CD4, CBC, and liver function tests (LFTs) were conducted and the results were collected as base information and, during and after the treatment, clinical statuses of the patients, treatment progress, and laboratory information were recorded in the files.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070423046N1**
Registration date: **2015-09-10, 1394/06/19**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-09-10, 1394/06/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Qom Branch Of Islamic Azad University

Expected recruitment start date

2013-08-05, 1392/05/14

Expected recruitment end date

2014-02-09, 1392/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Adjuvant IMOD therapy on the Immunological Status of HIV-positive Patients: A Random Controlled Clinical Trial

Public title

The effect of adding IMOD Iranian drug in HIV-positive patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: HIV-positive patients (with two positive ELISA tests and a positive Western blot test) with Indications for treatment with HAART regimen Exclusion criteria: The patient withdrew from the study of cooperation
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization were Simple randomly.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qom Univercity of Medical Science
Street address
Qom Univercity of medical science , Saheli Street , Qom
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Qom
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Approval date
2015-06-18, 1394/03/28
Ethics committee reference number
IR.MUQ.REC.1394.30

Health conditions studied

1

Description of health condition studied
AIDS
ICD-10 code
B20-B24
ICD-10 code description
Human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description
CD4 (cluster of differentiation 4)
Timepoint
Before and after the interventions(After 90 days)
Method of measurement
Flow cytometry

2

Description
TLC (Total lymphocyte count)
Timepoint
Before and after the interventions(After 90 days)
Method of measurement
CBC Diff

Secondary outcomes

1

Description
BUN , Cr
Timepoint
Before and after the interventions(After 90 days)
Method of measurement
Routine laboratory scale measurements

2

Description
liver function tests (LFT)
Timepoint
Before and after the interventions(After 90 days)
Method of measurement
Routine laboratory scale measurements

Intervention groups

1

Description
Intervention group: patients underwent IMOD infusion in addition to HAART therapy. IMOD vials contain 120 mg in 4 cc. It was diluted in 50 to 100 ml of 5% dextrose and administrated within half an hour through intravenous infusion (IV). The maximum duration of IMOD infusion was 90 days (daily injections. *The HAART regimen used in both groups.
Category
Treatment - Drugs

2

Description

Control group: The HAART regimen that includes 1 NNRTI + 2 NRTI. *nucleoside reverse transcriptase inhibitors (NRTIs) **non-nucleoside reverse transcriptase inhibitors (NNRTIs)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Counseling Center For Behavioral Diseases in Qom

Full name of responsible person

Ghasem Amiri

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22th Street, Bu Ali Street, Istgah Avenue, Qom

City

Qom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Of Qom Branch Of Islamic Azad University - Counseling Center for Behavi

Full name of responsible person

Dr.Ghasem Amiri

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Qom

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 Qom Branch Of Islamic Azad University - Counseling Center for Behavi

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

Qom Branch Of Islamic Azad University

Full name of responsible person

Mehdi Gholamzadeh Baees

Position

Student Of M.D

Other areas of specialty/work

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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