Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trial of IMOD in HIV/AIDS patients

Protocol summary

Summary

HIV /AIDS is a worldwide infection. Treatment of patients is an important challenge for physicians. IMOD has been registered in Islamic Republic of Iran for treatment of HIV/AIDS patients. It is an immunomudolatory drug and can significantly increase the CD4 lymphocyte number in these patients. This study will be conducted as a phase II clinical trial without control group in Syria. Patients will be recruited in Damascus AIDS center. The inclusion criterion is: patients having CD4 lymphocyte count less than 400. Patients will receive IMOD for 3 months with standard antiviral medications. Main exclusion criteria: Evidence of malignancy, Presence of life threatening conditions such as hepatic or renal failure or congestive heart failure, Presence of life threatening infections or other serious and dangerous infections, Presence of liver function disorders in laboratory tests including elevation of liver enzymes or Bilirubin level more than 3 times of the upper limit of the normal range, Treatment with corticosteroids, immune suppressants, radiotherapy or chemotherapy. 15 HIV positive patients having the eligibility criteria will be recruited. Written informed consent will be obtained. All subjects will receive intravenous IMOD equivalent of 100 mg active ingredient daily for 3 month. CD4 lymphocyte count, viral load and quality of life in patients will be assessed before and after receiving the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904084272N1**
Registration date: **2010-08-26, 1389/06/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-08-26, 1389/06/04

Registrant information

Name

Dr Faten Al akkad

Name of organization / entity

Ministry of Health, Syria

Country

Syrian Arab Republic

Phone

00963112758133

Email address

dqc.dir@moh.gov.sy

Recruitment status

Recruitment complete

Funding source

Pars Roos Biotechnology Company, Tehran, Iran

Expected recruitment start date

2010-07-11, 1389/04/20

Expected recruitment end date

2010-12-11, 1389/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of IMOD in HIV/AIDS patients

Public title

Phase II single arm clinical trial to evaluate safety and efficacy of IMOD in HIV/AIDS patients in Syria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria • Diagnosis of HIV infection (two positive ELISA confirmed by one positive Western Blot test) • Receiving HAART • Age more than 18-75 Exclusion criteria • Evidence of malignancy (diagnosed or presenting a sign or symptom of major cancer such as hemoptysis, chronic cough, rectal bleeding, etc) except

for Kaposi’s sarcoma • Presence of life threatening conditions such as hepatic or renal failure or congestive heart failure • Presence of life threatening infections or other serious and dangerous infections • Presence of liver function disorders in laboratory tests including elevation of liver enzymes or Bilirubin level more than 3 times of the upper limit of the normal range • Drug and alcohol abuse (more than 21 units alcohol for males and 14 units for females) • Treatment with corticosteroids, immune suppressants, radiotherapy or chemotherapy • Any known drug hypersensitivity • Inability or refusal to sign the informed consent • Receiving any investigational drug within 30 days prior to screening • Pregnancy or intention of becoming pregnant during the study period

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Syria Ministry of Health Ethics committee

Street address
Ministry of Health, Damascus, Syria

City
Damascus

Postal code

Approval date
empty

Ethics committee reference number
6504

Health conditions studied

1

Description of health condition studied
HIV/ AIDS

ICD-10 code
B24

ICD-10 code description
Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes

1

Description
CD4 Lymphocyte count

Timepoint
At the beginning, First, second, third and fourth month of study.

Method of measurement
Flocytometry

Secondary outcomes

1

Description
Viral load

Timepoint
At the beginning and end of the study.

Method of measurement
Real Time Polymerase Chain Reaction test

2

Description
Quality of life

Timepoint
At the beginning and end of the study.

Method of measurement
Questionaire

Intervention groups

1

Description
Intrvenous injection of IMOD one vial daily for three months. Each vial contains 4ml IMOD. It will be diluted in 100ml of dextrose 5% solution before injection and will be administered within one hour

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Damascus AIDS center

Full name of responsible person
Dr. Rana Alayazra

Street address
Damascus AIDS center, Al zablataaneh
City
Damascus

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pars Roos Biotechnology Co.
Full name of responsible person
Dr. Koorosh Kamali
Street address
No 568, 13 th Alley, Hormozan St., Shahrak-e- gharb
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pars Roos Biotechnology Co.
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
Clinical trial Department
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Person responsible for updating data

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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