

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of safety and efficiency of curcumin in the immune system and viral load of patient with HIV

Protocol summary

Study aim

Determining the effectiveness of nanocurcumin on the immune system of patients with HIV

Design

In this project, participants in two control groups who use only basic drugs for the treatment of HIV and intervention group who in addition to basic drugs use nanocurcumin according to the protocol. The number of participants in this project is 100 people who are divided into two groups of 50 people. They are divided into two groups accidentally.

Settings and conduct

In this project, 50 HIV-infected patients who refer to the Behavioral Diseases Counseling Center of Imam Khomeini Hospital will be examined for one year, and every 6 months blood CD4 count and viral loads will be tested. It is performed annually for them and patients are re-examined for safety and viral load after treatment with nanocurcumin.

Participants/Inclusion and exclusion criteria

Terms of participation in the project • Having informed and voluntary consent in writing • The patient has two reactive HIV ELISA tests. People who have the following conditions at the beginning of the study will not be included in the study: • The number of viruses in their blood is undetectable. • The patient has hepatitis B or C. • Pregnancy and lactation • Current drug or alcohol use • Growth hormone use (30 days before enrollment) Use of testosterone or anabolic steroids (30 days before enrollment) Long-term treatment with immunosuppressive drugs (except topical steroids) Chemotherapy, interferon therapy or radiotherapy (three weeks before enrollment)

Intervention groups

Intervention group: A group that uses nanocurcumin in addition to basic drugs to treat HIV. This drug contains curcumin, which is active except turmeric root. The other two main curcuminoids (dimethoxy curcumin and bis dimethoxy curcumin) are also components of this drug.

This medicine is a 40 mg tablet daily for 3 months.

Main outcome variables

Viral load and CD4 T cell count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050373N4**

Registration date: **2022-05-28, 1401/03/07**

Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

Registration date

2022-05-28, 1401/03/07

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

2022-07-06, 1401/04/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of safety and efficiency of curcumin in the immune system and viral load of patient with HIV

Public title
The evaluation the effect of nanocurcomin in people living with HIV

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
people with positive test (PCR) people with positive test (Elisa)
Exclusion criteria:
Patient with hepatitis B Patient with hepatitis C
Pregnancy Breastfeeding Alcohol and Drug use Use of Growth Hormone (at least 30 days before the study) Use of Immunosuppressive drugs Use of Testosterone and Anabolic Steroids (at least 30 days before the study) Under Chemotherapy with Interferon or Radiotherapy Patients with Undetectable viral loads

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method will be used. Random number table is a set of numbers that are generated completely randomly and are tabulated. Firstly, we determine the direction of the random number table and then we decide to read the random number table from above. Then we consider even numbers for the intervention group and odd numbers for the control group.

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
Ethics committee of Imam khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Imam Khomeini Hospital Complex, Tohid Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2022-03-15, 1400/12/24
Ethics committee reference number
IR.TUMS.IKHC.REC.1400.529

Health conditions studied

1

Description of health condition studied
The effect of nanocurrcomin in HIV treatment
ICD-10 code
HIV
ICD-10 code description

Primary outcomes

1

Description
counting CD4 test
Timepoint
30 days after first use
Method of measurement
with Flow cytometry instrument

2

Description
viral load test
Timepoint
30 days after first use
Method of measurement
آزمایش PCR

Secondary outcomes

empty

Intervention groups

1

Description
Control group: A group that only takes routine HIV medications.
Category

Treatment - Drugs

2

Description

Intervention group: A group that uses nanocurcumin in addition to basic drugs to treat HIV. This drug contains curcumin, which is active except turmeric root. The other two main curcuminoids (dimethoxy curcumin and bis dimethoxy curcumin) are also components of this drug. This medicine is a 40 mg tablet daily for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

HIV research center Emam Khomeini hospital

Full name of responsible person

Abbas Bahrami

Street address

Blvd Keshavarz Emam hospital HIV research center

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1583

Email

bahramiab34@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice Chancellor of Research, Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

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Tehran

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1417653761

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

SeyedAhmad SeyedAlinaghi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Epidemiology

Street address

Tehran,keshavarz Blvd,Emam khomeini hospital,HIV research center

City

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s_a_alinaghi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

SeyedAhmad SeyedAlinaghi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Epidemiology

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Abdoli
Position
researcher
Latest degree
Master
Other areas of specialty/work
Laboratory Medicine
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City
Tehran
Province
Tehran
Postal code

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