Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 nanocrocumine 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 nanocurcommin 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
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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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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
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Person responsible for scientific inquiries

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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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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