

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

The effect of probiotic supplementation Lactobacillus Rhamnosus (RC-14) and Lactobacillus Reuteri (GR-1) on increasing the number of CD4 in HIV patients, A double blind randomized clinical trial with a placebo control.

Protocol summary

Summary

The purpose of the study and design of the study: The effect of probiotic on the increase in the number of CD4 compared to placebo in patients with HIV who are not treated with Highly Active Anti Retroviral Therapy (HAART), Randomized, double blind, placebo controlled, single center, prospective phase 2, Study population and method: Fifty HIV patients referred to the behavioral health counseling center, Imam Khomeini in 1395 to 1396 years with the main inclusion criteria : confirm HIV infection by Western blot analysis; lack of criteria for initiating treatment according to national HIV guideline; no use of probiotic supplements in the past 6 months; have a consent to conduct research , and Main exclusion criteria: active addiction; opportunistic infection in the past ; Liver or Kidney failure; active infection and fever; have a cancer and pregnancy or breastfeeding; a history of allergy or sensitivity to the probiotic or lactose intolerance , are randomized to allocate in intervention group with probiotic capsules containing (Lactobacillus Rhamnosus GR-1 and Lactobacillus Reuteri RC-14) taking every 12 hours and placebo group with placebo capsules taking every 12 hours, for 6 months , The CD4 and the CRP of patients are measured before, 12 weeks and 24 weeks after treatment in two groups, the outcome of the study: use of probiotic in comparison with placebo can increase the number of CD4 (least significant difference based on similar studies in the past is 15 number of CD4) in patients with HIV.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092228308N1**

Registration date: **2016-09-22, 1395/07/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-22, 1395/07/01

Registrant information

Name

Ali Asadollahi Amin

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 0856

Email address

emadiham@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Tehran University of Medical Sciences. Zist Takhmir Company.

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic supplementation Lactobacillus Rhamnosus (RC-14) and Lactobacillus Reuteri (GR-1) on increasing the number of CD4 in HIV patients, A double blind randomized clinical trial with a placebo control.

Public title

The effect of probiotic in HIV patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirm HIV infection by Western blot analysis; lack of criteria for initiating treatment according to national HIV guideline; no use of probiotic supplements in the past 6 months ; have a consent to conduct research Exclusion criteria: On Highly Active Anti Retroviral Therapy (HAART) regimens; active addiction; opportunistic infection in the past; Liver or Kidney failure; inflammatory bowel disease and other well known Gastrointestinal pathology; active infection and fever; younger than 18 and older than 65 years; have a cancer, pregnancy and breastfeeding; being dependent on alcohol; a history of allergy or sensitivity to the probiotic or lactose intolerance; use of other supplement drugs, and multivitamins; Use of growth hormone, testosterone or anabolic agent during the last 6 months.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Permuted block randomization

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Hospital Ethics Committee Imam Khomeini, Tehran
University of Medical Sciences

Street address

End of Keshavarz Blvd., Imam Khomeini Hospital .

City

Tehran

Postal code**Approval date**

2016-08-09, 1395/05/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.416

Health conditions studied**1****Description of health condition studied**

HIV

ICD-10 code

B24

ICD-10 code description

Unspecified human immunodeficiency virus [HIV] disease

Primary outcomes**1****Description**

CD4

Timepoint

At baseline ,three months later, and after 6 months.

Method of measurement

Based on the number per microliter by laboratory blood tests

Secondary outcomes**1****Description**

CRP

Timepoint

At baseline ,three months later, and after 6 months.

Method of measurement

Based on the number per microliter by laboratory blood tests

2**Description**

Side effects

Timepoint

every 4 week after intervention

Method of measurement

Based on side effects checklist

Intervention groups**1****Description**

Zist Takhmir Company probiotic capsules containing (Lactobacillus Rhamnosus GR-1 and Lactobacillus Reuteri RC-14 10⁹ colony forming units), one capsule every 12 hours for 24 weeks.

Category

Treatment - Drugs

2

Description

One Placebo capsule every 12 hours for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Behavioral health counseling center, Imam Khomeini.

Full name of responsible person

Mrs. Dr. Siami

Street address

Imam Khomeini Hospital, End of Keshavarz Blvd.,
Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Tehran University of
Medical Sciences

Full name of responsible person

Miss Moamaei

Street address

Tehran University of Medical Sciences Headquarters,
Keshavarz Blvd., First of Gods St., Tehran

City

Tehran

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 Tehran University of Medical
Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Zist Takhmir Company

Full name of responsible person

Dr. Mohammadi

Street address

No. 597, Before Heydarkhani Cross, Eastern Farjam
St., Resaalat Sq., Tehran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Takhmir Company

Proportion provided by this source

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

Tehran University of Medical Science

Full name of responsible person

Dr. Ali Asadollahi Amin

Position

Infectious disease specialist

Other areas of specialty/work

Street address

Unit 1, Floor1, No. 51, Shahid Sadat Ave., Darvazeh
Shemiran, Tehran

City

Tehran

Postal code

Phone

+98 21 7752 0856

Fax

Email

amiyaneh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Dr. Ali Asadollahi Amin

Position

Infectious disease specialist

Other areas of specialty/work

Street address

Unit 1, Floor1, No. 51, Shahid Sadat Ave., Darvazeh
Shemiran, Tehran.

City
Tehran
Postal code
Phone
+98 21 7752 0856
Fax
Email
amiyaneh@gmail.com
Web page address

Tehran
Postal code
Phone
+98 21 7752 0856
Fax
Email
amiyaneh@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Dr. Ali Asadollahi Amin
Position
Infectious disease specialist
Other areas of specialty/work
Street address
Unit 1, Floor1, No. 51, Shahid Sadat Ave., Darvazeh
Shemiran, Tehran.
City

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