

# 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 10<sup>9</sup> 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

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## 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**  
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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*