

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Probiotic Pill on Oral Candida in HIV Positive Patients with Immunologic Failure

Protocol summary

Study aim

Determination of the Effect of Probiotic Tablets on the Number of Oral Candida Colonies in Patients Afflicted with HIV with Immunologic Failure of Patients Referring to West Tehran Health Center

Design

In This Study, 30 HIV-positive People, who despite the Success of a Virological Treatment with Immunological Failure, are eligible for Inclusion in a Study That is under the Supervision of Tehran Health Center in Tehran. Participants are Unrandomly divided into Intervention and Control Groups, Each assigned a Code.

Settings and conduct

This Research Was Unrandomized By Allocating Patients To Two Groups Of Odd And Even Based On The Case Number. All Patients With Definite HIV Diagnosis Who Referred To The West Health Center For Treatment And Despite The Virologic Success Of The Poor Immune System, One MI Of Oral Saliva Was Taken From Each Person And Transferred To The Microbiology Department Of Shahid Beheshti University In The Standard Environment. In Saboro Dextrose Agar, The Number Of Candidate Colony Was Determined In Terms Of CFU.MI. Patients Were Unrandomly Divided Into Two Groups Of Intervention And Control The Intervention Group Received Probiotic Pill Daily 2 Tablets For 1 Month And Anti-Retroviral Therapy And Control Group Just Anti-Retroviral Therapy

Participants/Inclusion and exclusion criteria

HIV positive People with Immunological Failure who have not been using Antibiotics since 1 Month Prior to the Sampling and Duration of the Study, have not been Using Probiotic Products, and have Collaborated and have a Positive Salivary Candidate Patients who do not have Conditions are not Included in the Study

Intervention groups

The Intervention Group is the Patients who receives ART and Probiotic Pill and for Control Group is ART

Main outcome variables

Reduced Oral Candidia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170618034619N2**

Registration date: **2017-12-11, 1396/09/20**

Registration timing: **retrospective**

Last update: **2017-12-11, 1396/09/20**

Update count: **0**

Registration date

2017-12-11, 1396/09/20

Registrant information

Name

Tarane Farrokhnia

Name of organization / entity

Azad Islamic University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

t_farrokhnia@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Probiotic Pill on Oral Candida in HIV Positive Patients with Immunologic Failure

Public title

The Effect of Probiotic Pill on Oral Mushroom in HIV-positive Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

HIV positive People who have an Immunological Failure
HIV positive People who have a Positive Salivary Candidate

Exclusion criteria:

HIV positive People with an Immunologic Failure that take Antibiotics
HIV positive people with an Immunologic failure who have taken an Anti-fungal Drug
HIV-positive people with an Immunologic Failure that has consumed Probiotic Products
HIV positive people with an Immunologic Failure who are not Cooperatives

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **13**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran Azad University of Dentistry

Street address

No.9, Ninth Neyestan Alley, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,8

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

Oral Candida

ICD-10 code

Candidiasis

ICD-10 code description

B37

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

Candida Colony Count

Timepoint

At the Beginning of the Study (before the Intervention) and 1 Month after taking the Tablet

Method of measurement

CFU with Microbiological laboratory Methods

Secondary outcomes

empty

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

Intervention group: Probiotics / 10,000,000,000 colonies per ml / 2 times a day for 1 month and Anti-Retroviral Therapy

Category

Treatment - Drugs

2**Description**

Control group: Anti-Retroviral Therapy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran West Health Center

Full name of responsible person
Saeed Kalantari
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Islamic Azad University
Full name of responsible person

Tarane Farrokhnia
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

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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