

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The investigation of six months concurrent training effects on inflammatory markers, growth factors and bone mineral density of HIV positive patients

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of six_month concurrent training on inflammatory markers, growth factors and bone mineral density of HIV positive patients

Design

Current study is a clinical trial with parallel group design and 30 eligible persons will randomly assign to one of intervention (15) and control group (15)

Settings and conduct

location of conducting current project is Tehran Positive Club situated in Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

1- Between 18-60 years old 2- Do not having active addiction 3- Being interest for participation in study 4- Being under stable anti retro viral therapy for previous six months 5- Did not have regular exercise training in previous six months 6- Have stable ART in previous six months 7- Do not have situations that susceptible participants to bone loss .

Intervention groups

The participants in the intervention group for six months performing concurrent training, and we will asking from participants in the control group to maintain their levels of physical activity during study period.

Main outcome variables

Bone Mineral Density (BMD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100601004076N21**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Minoo Mohraz

Name of organization / entity

Iranian Research Center for HIV/AIDS, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-23, 1397/03/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of six months concurrent training effects on inflammatory markers, growth factors and bone mineral density of HIV positive patients

Public title

Exercise therapy for HIV+ patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18-60 years old Do not have active addiction at the initiation of study having interest to participate in study Being under stable anti retro-viral therapy for previous six month

Exclusion criteria:

using drugs that have affect on bone mineral density participate in regular exercise training in previous six months

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible volunteers will randomly be assigned to intervention and control groups. randomization will be done by a randomization list that will be generated by computerized software program

Blinding (investigator's opinion)

Not blinded

Blinding description

Due to nature of this study it is not possible to blind participants and researchers to benefits of intervention

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethical committee of Tehran University of Medical Sciences

Street address

Central building of TUMS, Ghods St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

0123456789

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1863

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

Human immunodeficiency virus [HIV] disease

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease

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

Bone Mineral Density(BMD)

Timepoint

pre and post study period

Method of measurement

Dual-energy X-ray absorptiometry

Secondary outcomes

empty

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

Intervention group: The participants in the intervention group will participate in concurrent training for six months and three times a week. concurrent training involves a combination of aerobic training and resistance training, resistance training with an emphasis on the large muscles groups . In order to maintain the overload, the training variables such as the intensity and volume of exercise, resistance training and aerobic training manipulate according to patient progression. To maintain the principle of overload.

Category

Lifestyle

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

Tehran positive club

Full name of responsible person

Nasrin Kordi

Street address

Tehran positive club,Imam Khomeini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Dr Minoo Mohraz
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable