

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Seroepidemiology of Diphtheria and Tetanus antibodies and response to the booster dose of Td in HIV infected patients

Protocol summary

Summary

HIV positive patients are at risk of super infection according to their immunity level. Prevention from other infections is an effective and important activity for control the immune level in this group. According to previous studies PLWHIV have a positive response to DT vaccination but these Ab are not remain in the steady level and decreasing after awhile. In this study we want to asses the seroepidemiology of TD vaccination in PLWHIV and if they are negative , evaluating the level of Ab in blood samples after vaccination in routine. This is a clinical trial for assessment of immune resoins to TD vaccination in HIV positive patients. According to the inclusion criteria which was mentioned at this page our participants involve in this study and at the beginning Titer of antibody for TD will evaluate and if it is under the standard rate they will vaccinate with TD vaccine and the antibody titer will recheck after 1 and 6 months . Objectives: 1-Evaluation the TD antibody level in HIV patients. 2-Evaluattion of TD antibody level continuation in HIV patients 3- Evaluating CD4 count at the time of study and relation between CD\$ and antibody level

General information

Acronym

TD vaccination

IRCT registration information

IRCT registration number: **IRCT201211204076N8**

Registration date: **2012-12-25, 1391/10/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-25, 1391/10/05

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)

Phone

+98 21 6694 7984

Email address

minoomohraz@ams.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Seroepidemiology of Diphtheria and Tetanus antibodies and response to the booster dose of Td in HIV infected patients

Public title

Evaluation of the immune system response to Diphtheria and Tetanus vaccination in HIV positive patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age above 18 and under 65 years; accepting the consent form and unresponsive to previous vaccination Exclusion criteria: pregnancy; age under 18

and above 65 years and positive antibody for Diphtheria and Tetanus.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Tehran university of medical sciences

Street address

Central building of TUMS, Ghods St, Keshavarz Blvd,
Valiasr Sq

City

Tehran

Postal code**Approval date**

2012-11-26, 1391/09/06

Ethics committee reference number

91-03-55-19400-69709

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

HIV AIDS

ICD-10 code

B20

ICD-10 code description

Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases

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

DT Antibody

Timepoint

Before vaccination, 1 and 6 month after vaccination

Method of measurement

Serum antibody level

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

CD4 count

Timepoint

Before vaccination

Method of measurement

flowcytometry

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

According to basic level of Diphtheria and Tetanus serum antibody, if the Ab level is under the baseline for protection of our patients, we will vaccinate them and then at 1 and 6 month after vaccination we will asses the serum Ab .

Category

Prevention

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

Triangular clinic for sexual and behavioral disease.

Full name of responsible person

Minoo Mohraz

Street address

Iranian Research Center for HIV/AIDS, Imam
Hospital.keshavarz Blvd

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Resaerch Deputy tehran university of medical
sciences

Full name of responsible person

Dr Fotoohi

Street address

Ghods Avn , Keshavarz Blvd

City

Tehran

Grant name

غير مستقل، گزنت ساليانه مركز تحقيقات

Grant code / Reference number

19400

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

Yes

Title of funding source

Resaerch Deputy tehran university of medical sciences

Proportion provided by this source

100

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**

Iranian research Center for HIV AIDS (IRCHA)

Full name of responsible person

Minoos Mohraz MD

Position

Head of IRCHA

Other areas of specialty/work**Street address**

Iranian research Center for HIV AIDS (IRCHA),Imam Hospital, Keshavarz BLVD , Valiasr Sq

City

Tehran

Postal code**Phone**

+98 21 6694 7984

Fax**Email**

ircha@tums.ac.ir

Web page address

ircha.tums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iranian research center for HIV AIDS

Full name of responsible person

Minoos Mohraz MD

Position

Professor

Other areas of specialty/work**Street address**

Iranian research center for HIV AIDS, Imam Hospital, Keshavarz BLVD , Valiasr Sq

City

Tehran

Postal code**Phone**

+98 21 6694 7984

Fax**Email**

ircha@tums.ac.ir

Web page address

ircha.tums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iranian Research Center for HIV/AIDS

Full name of responsible person

Maryam Foroughi

Position

MD

Other areas of specialty/work**Street address**

Iranian Research Center for HIV/AIDS, Imam Hospital, Keshavarz BLVD

City

Tehran

Postal code**Phone**

+98 21 6694 7984

Fax**Email**

ma_foroughi@yahoo.com

Web page address

ircha.tums.ac.ir

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