Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 resoinse 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

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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 Diphteria 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
flowcytometery

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

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Ghods Avn , Keshavarz Blvd

City
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Grant name
غیر مستقل، گرنت سالیانه مرکز تحقیقات
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
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Person responsible for updating data

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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