Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the association of HSV2 infection in HIV progression in HIV positive patients.

Protocol summary

Summary

There are limited numbers of studies which have been done on role of herpes simplex virus type-2 (HSV-2) infection on human immunodeficiency virus (HIV)-1 progression among HIV infected patients. This study will be a Randomized double blind placebo-controlled trial study and will be done in two phases. First phase: 90 HIV positive patients with positive serology for HSV-2 and 90 HIV positive patients without this marker as a control group will be recruited in this study. The participants in both groups will be followed up and compared in respect of HIV progression toward AIDS. This follow up will consist of CD4 count and HIV-1 viral load checking in first recruitment (baseline) and then after 1 year. These two groups will be compared regarding HIV progression toward AIDS. Inclusion criteria include: HIV positive patients with CD4 count of 400-900 cells/mm3 and not being under antiviral therapy. Second phase: Through this phase, clinical trial with two parallel RCT will be done. In this purpose, HIV-1/HSV-2 co-infected patients will be divided in two groups and will be treated randomly by Acyclovir versus placebo. Two groups will be checked and compared based on CD4 count and HIV-1 viral load after one year.

General information

Acronym

Evaluating the association of HSV2 in HIV infection

IRCT registration information

IRCT registration number: **IRCT201311094076N12**
Registration date: **2014-01-12, 1392/10/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-12, 1392/10/22

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

Resaerch Deputy tehran university of medical sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-07-21, 1393/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the association of HSV2 infection in HIV progression in HIV positive patients.

Public title

Evaluating the association of HSV2 infection in HIV progression in HIV positive patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: HIV positive patients referred to Iranian Research Center for HIV/AIDS-Imam Khomeini Hospital with CD4 count of 400-900 cells/mm3 and not

being under antiviral therapy. Exclusion criteria: CD4 count above 400-900 cells/mm3; co infected with either HBV or HCV; having genital wart.

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iranian Research Center for HIV/AIDS

Street address
Imam Hospital. Keshavarz Blvd, Tehran

City
Tehran

Postal code

Approval date
2013-11-22, 1392/09/01

Ethics committee reference number
92-02-55-23696

Health conditions studied

1

Description of health condition studied
HIV AIDS

ICD-10 code
B24

ICD-10 code description
Human immunodeficiency virus [HIV]

Primary outcomes

1

Description
CD4 Count

Timepoint
1 year after intervention and starting for treatment

Method of measurement
Blood Test

2

Description
Viral Load

Timepoint
1 year after intervention and starting for treatment

Method of measurement
Blood Test

Secondary outcomes

1

Description
HIV progression

Timepoint
1 year after starting the project

Method of measurement
lab tests and physical exams

Intervention groups

1

Description
Intervention Group: Through this phase, clinical trial with two parallel RCT will be done. In this purpose, HIV-1/HSV-2 co-infected patients will be divided in two groups, 45 participants in each group and will be treated randomly by Acyclovir . Two groups will be checked and compared based on CD4 count and HIV-1 viral load after one year.

Category
Treatment - Drugs

2

Description
Control Group: 45 HIV HSV2 positive participants will be recruit in this phase as control group , there is no drug treatment or intervention for this group. After 1 year from the study baseline we will get a blood test for evaluate CD4 count and viral load for comparing with intervention group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Research Center for HIV/AIDS

Full name of responsible person

Minoo Mohraz

Street address

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

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Resaerch Deputy tehran university of medical sciences

Full name of responsible person

Dr. Masoud Younesian

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Ghods Avn , Keshavarz Blvd Tehran Iran, Islamic Republic Of

City

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Grant name

غیر مستقل، گرنت سالیانه مرکز تحقیقات

Grant code / Reference number

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

Minoo Mohraz MD

Position

Head of IRCHA

Other areas of specialty/work

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Web page address

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