Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing efficacy of dolutegravir plus tenofovir alafenamide as dual-drug regimen with the standard triple-drug regimen in HIV positive patients

Protocol summary

Study aim

This study has been designed to compare efficacy of dolutegravir plus tenofovir alafenamide as a double-drug regimen with the standard triple-drug redimen in HIV positive patients with undetectable viral load.

Design

This is an open-label randomized clinical trial. Eighty HIV positive patients will be assigned to the intervention or the control group according to the simple randomization method.

Settings and conduct

Patients who referred to the HIV clinic of Imam Khomeini Hospital Complex (affiliated with Tehran University of Medical Sciences) for their treatment follow-up will be evaluated for the inclusion criteria of the study. Eligible patients will be included in study after that sign the consent form.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: -Adults older than 18 years old -HIV positive patients with undetectable viral load for at least 2 years -HIV positive patients with CD4 cells count >200 for at least 2 years -Patients who are on first line antiretroviral therapy for at least 2 years -No any mutation against INSTI or NRTI drugs -Adequate adherence to treatment -No any AIDS-related event (opportunistic infection or cancer) Exclusion criteria are: -Pregnant or lactating women -Concomitant viral co-infections including hepatitis B or C -Existing any co-morbidity that requiring treatment which may have significant interactions with ART -Renal or hepatic diseases

Intervention groups

Intervention group : Standard ART regimen (triple-drug regimen) will be changed to dual regimen including dolutegravir plus tenofovir alafenamide (DTG plus TAF) Control group: The patients' standard regimen (triple-drug regimen) will be continued. Duration of intervention and follow-up in the both groups is 48 weeks.

Main outcome variables

HIV viral load CD4 cells count Adverse drug reactions Adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191005044984N1**
Registration date: **2019-12-21, 1398/09/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-21, 1398/09/30**
Update count: **0**

Registration date

2019-12-21, 1398/09/30

Registrant information

Name

Golbarg Alavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1598

Email address

golbarg.alavian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy of dolutegravir plus tenofovir alafenamide as dual-drug regimen with the standard triple-drug regimen in HIV positive patients

Public title

Dolutegravir plus tenofovir alafenamide as a double-drug regimen in HIV positive patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults older than 18 years old HIV positive patients with undetectable viral load for at least 2 years HIV positive patients with CD4 cells count >200 for at least 2 years Patients who are on first line antiretroviral therapy for at least 2 years No any mutation against INSTI or NRTI drugs Adequate adherence to treatment No any AIDS-related event (opportunistic infection or cancer)

Exclusion criteria:

Pregnancy and lactation Concomitant viral co-infections including hepatitis B or C Existing any co-morbidity that requiring treatment which may have significant interactions with ART Renal or hepatic diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to the intervention or the control group using simple randomization method. The random numbers will be created by a computer program. The random numbers will be sent to satellite pharmacy of the HIV clinic. Eligible patients will be introduced to this department and treatment regimen will be assigned accordingly.

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 University Of Medical Scienses

Street address

Ghods Ave.

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.087

Health conditions studied

1

Description of health condition studied

Virologically Undetectable HIV Patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Virological response: Maintain HIV-RNA viral load <50 copies / ml in response to the ART regimen during the study course

Timepoint

Control group: At baseline and weeks 24 and 48
Intervention group: At baseline and weeks 8, 24 and 48

Method of measurement

LightCycler® 96 Real-Time PCR, Roche, with a limit of 40 copies / ml

2

Description

Immunological response: Increase or maintenance of CD4 cells count > 200 cells/mm3 during the study period

Timepoint

Control group: At baseline and weeks 24 and 48
Intervention group: At baseline and weeks 8, 24 and 48

Method of measurement

Flowcytometry

3

Description

Adverse reactions : Any new sign or symptom caused by the regimens

Timepoint

Control group: At baseline and weeks 24 and 48
Intervention group: At baseline and weeks 8, 24 and 48

Method of measurement

Interview and patient' report

4

Description

Adherence to treatment

Timepoint

Control group: At baseline and weeks 24 and 48
Intervention group: At baseline and weeks 8, 24 and 48

Method of measurement

Interview and pill count methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients' previous standard triple-drug regimen will be changed to the dual-drug regimen including dolutegravir tablet, 50 mg daily plus tenofovir alafenamide tablet, 25 mg daily. This change will be continued for 48 weeks. Patients will be followed during the study period.

Category

Treatment - Drugs

2

Description

Control group: The patients' previous standard triple-drug regimen will be continued. Patients will be followed for 48 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
HIV Clinic affiliated to Imam Khomeini Hospital Complex
Full name of responsible person
Ladan Abbassian
Street address
Imam Khomeini Hospital Complex, Gharib Ave., Keshavarz Blvd.
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Email
La.abbasian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran
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msahrai@sina.tums.ac.ir

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
Hossein Khalili
Position
Professor
Latest degree
Specialist
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript.
When the data will become available and for how long
One year after finishing the study, data will be published and will be available in databases.
To whom data/document is available
After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes.
Under which criteria data/document could be used
Other researchers are permitted to included the results in their systematic reviews and meta analysis.
From where data/document is obtainable
Contact scientific responsible person for the clinical trial as needed.
What processes are involved for a request to access data/document
After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks.
Comments