iPrEx-DISCOVER Weight Change Study

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The primary objective of this study is: To compare weight change/trajectory distributions between F/TAF and placebo cohorts. The secondary objectives of this study are: To compare outlier weight gain between F/TAF and...

Ethical review	Positive opinion
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57532

Source
Onderzoeksportaal

Brief title
iPrEx-DISCOVER Weight Change Study

Condition

- Viral infectious disorders

Synonym
Pre-Exposure Prophylaxis of HIV-1 Infection

Research involving
Data

Sponsors and support

Primary sponsor: Gilead Sciences
Source(s) of monetary or material Support: Gilead Sciences

Intervention

- Medicine

Explanation

N.a.

Outcome measures

Primary outcome

Weight outcomes In both studies, participant body weight (in kg) was measured at baseline and at multiple visits up to 120 weeks after baseline. All available weight data measured on or following baseline will be used in this analysis with a limited exception: if participants had multiple distinct visit dates within the “baseline” window, only the chronologically last visit date prior to treatment will be retained.

Secondary outcome

Covariates Available baseline demographics, clinical history, comorbidities, and other known factors prognostic for weight gain will be used. Participant comedications that may relate to weight change have been distilled from medication inventory files. If feasible, given recorded data, racial/ethnic group identity, and indicators of socioeconomic status like participant educational achievement may also be used as covariates.

Study description

Background summary

People with HIV (PWH) often experience weight gain both upon first initiating antiretroviral (ARV) treatment regimens for HIV, and over the course of their treatment experience beyond the first year of treatment. There is concern that outlier weight gain may result in emergent obesity-related comorbidities, such as cardiovascular events, diabetes, and hypertension. Observed weight gain among PWH has been attributed to a return to health phenomena and societal norms that impact both PWH and people without HIV (PWoH) (eg, diet and exercise). This concern is not limited to PWH, as there are observed global increases in the prevalence of obesity and obesity-related metabolic outcomes among the general populations (ie, PWoH). In this context, there are ongoing efforts to understand the role of specific ARV agents for HIV treatment and HIV prevention in weight change, and how weight change among those exposed to specific ARVs may or may not differ from weight change trajectories among PWoH with no exposure to ARVs.

Emtricitabine/tenofovir alafenamide (coformulated; Descovy®) (F/TAF) and emtricitabine/tenofovir disoproxil fumarate (coformulated; Truvada®) (FTC/TDF) are 2 fixed-dose combinations (FDCs) used in the treatment and prevention of HIV. There are data which demonstrate the weight-suppressive effect of FTC/TDF ; however the role of F/TAF

in weight change remains unclear .

In the present study, we propose to leverage data from 2 Phase 3 clinical studies, iPrEx (Study COUS1040288: FTC/TDF versus placebo) and DISCOVER (Study GSUS4122055: F/TAF vs FTC/TDF) to compare F/TAF with placebo weight trajectories, using the common FTC/TDF groups as a negative control to assess the validity of the primary analysis results. The results of this study will provide a valuable understanding of the role of F/TAF in weight change both among PWH using F/TAF for treatment and PWoH using F/TAF for HIV prevention.

Study objective

The primary objective of this study is:

- To compare weight change/trajectory distributions between F/TAF and placebo cohorts.

The secondary objectives of this study are:

- To compare outlier weight gain between F/TAF and placebo cohorts.
- To describe incidence of weight-related comorbidities (ie, cardiovascular events, diabetes, and hypertension) in F/TAF, FTC/TDF and placebo cohorts.

Study design

This study will utilize existing data collected during 2 large Phase 3 clinical studies of FTC/TDF and F/TAF (iPrEx: 2007-2011 and DISCOVER: 2016-2019) to conduct an indirect comparison of F/TAF (DISCOVER) and placebo treatment groups (iPrEX), using the common FTC/TDF treatment groups as negative controls. The iPrEx study enrolled HIV seronegative adult men who have sex with men (MSM), at high risk for acquisition of HIV infection, in Brazil, Ecuador, Peru, South Africa, Thailand, and the United States (US). DISCOVER enrolled adult men and transgender women (TGW) who have sex with men, at high risk for acquisition of HIV infection in Austria, Canada, Denmark, France, Germany, Ireland, Italy, the Netherlands, Spain, the United Kingdom (UK), and the US.

Intervention

Emtricitabine/tenofovir alafenamide (coformulated; Descovy®) (F/TAF) and emtricitabine/tenofovir disoproxil fumarate (coformulated; Truvada®) (FTC/TDF) are 2 fixed-dose combinations (FDCs) used in the treatment and prevention of HIV.

Study burden and risks

None, this study is conducted with already existing data (secondary use of data).

Contacts

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Trial sites

Listed location countries

Brazil, Canada, Netherlands, Ecuador, Germany, Italy, Austria, Spain, Thailand, South Africa, Denmark, Ireland, United Kingdom, France, Peru, United States

Eligibility criteria

Age
Not applicable

Inclusion criteria

1. All inclusion criteria from the iPrEx and DISCOVER studies apply (see protocol Appendix 5),
   except where superseded by the exclusion criteria listed below.
2. Participants must have at least 1 record of measured body weight.

Exclusion criteria

1. All exclusion criteria from the iPrEx and DISCOVER studies apply (see protocol Appendix 5).
2. Transgender women recruited to the DISCOVER study.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-03-2025
Enrollment:	61
Type:	Anticipated

WORLD

Recruitment status:	Pending
Start date (anticipated):	31-03-2025
Enrollment:	7533
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	emtricitabine/tenofovir alafenamide
Product type:	Medicine
Generic name:	emtricitabine/tenofovir disoproxil fumarate

IPD sharing statement

Plan to share IPD: Yes

Plan description
The results of this study will be submitted for publication. Authorship of study manuscripts and presentations at scientific conferences will follow the guidelines established by the

International Committee of Medical Journal Editors (https://www.icmje.org/). Any final manuscript will be submitted to regulatory authorities within 2 weeks after first acceptance for publication.

Ethics review

Positive opinion

Date:	14-05-2025
Application type:	First submission
Review commission:	nWMO adviescommissie Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
HMA-EMA catalogue of real-world data studies	EUPAS1000000509
Research portal	NL-009280