A Randomized, Open Label, Phase 4 Study Evaluating the Renal Effect of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir DF or other Tenofovir DF-containing Regimens (Ritonavir-boosted Atazanavir plus Emtricitabine/Tenofovir DF or Efavirenz /Emtricitabine/Tenofovir DF) compared to Ritonavir-boosted Atazanavir plus Abacavir/Lamivudine in Antiretroviral Treatment-naïve HIV-1 Infected Adults with eGFR ≥ 70 mL/min

First published: 13/04/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8598

Study ID

24883

DARWIN EU® study

No

Study countries

- Belgium
- France
- Ireland
- Spain
- United Kingdom

Study description

GS-US-236-0140: The proposed study is to be conducted to fulfill an EU post-approval commitment to investigate renal (kidney) function and markers of renal tubular function in HIV-1 infected treatment-naïve patients taking a regimen of Stribild (STB), a tenofovir (TDF)-containing regimen without cobicistat (COBI), or a regimen without TDF or COBI. The primary objective of the present study is to evaluate the effect of STB or other TDF-containing regimens (atazanavir boosted with ritonavir ATV/r plus Truvada FTC/TDF or Atripla EFV/FTC/TDF) on renal function, as assessed by markers of glomerular filtration rate in HIV-1 infected treatment naïve adults with eGFR ≥ 70 mL/min, compared to ATV/r plus Kivexa (ABC/3TC). Additionally the pharmacokinetics (PK) of COBI, RTV and TFV and selected antiviral drugs in subjects' regimens will be evaluated.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

Institution | Pharmaceutical company

Multiple centres: 29 centres are involved in the study

Networks

UK CRN

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosures@gilead.com

Study contact

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Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2014

Actual: 01/04/2014

Study start date
Planned: 15/12/2014

Actual: 15/12/2014

Date of final study report
Planned: 30/09/2016

Actual: 11/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead

Study protocol

GS-US-236-0140_Protocol Original_28Aug14.pdf (844.42 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

If ‘other’, further details on the scope of the study

To investigate renal fuction in HIV-1 infected treatment naive patients.

Main study objective:

To investigate renal function and markers or renal tubular function in HIV-1 infected treatment-naïve patients taking a regimen of STB, a TDF-containing regimen without COBI, or a regimen without TDF or COBI. The primary objective of the present study is to evaluate the effect of STB or other TDF-containing regimens on renal function, as assessed by markers

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial phase

Therapeutic use (Phase IV)

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Medicinal product name

NORVIR

REYATAZ

STRIBILD

TRUVADA

Medical condition to be studied

HIV carrier

Population studied

Short description of the study population

HIV-1 infected treatment-naïve patients taking a regimen of Stribild (STB), a tenofovir (TDF)-containing regimen without cobicistat (COBI), or a regimen without TDF or COBI.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Immunocompromised

Estimated number of subjects

64

Study design details

Outcomes

To assess glomerular function before and during administration of STB or a regimen containing TDF without COBI as ATV/r plus FTC/TDF or EFV/FTC/TDF compared to a regimen containing neither TDF nor COBI as ATV/r plus ABC/3TC via determination of aGFR using iohexol (a probe GFR marker) plasma clearance and eGFR, To assess tubular function before and during administration of STB, ATV/r plus FTC/TDF, or EFV/FTC/TDF compared to a regimen of ATV/r plus ABC/3TC.To evaluate the pharmacokinetics, antiviral activity, efficacy, safety and tolerability of the three treatment regimens through 24 weeks of treatment.

Data analysis plan

Actual GFR, estimated GFR on each visit will be summarized by treatment group using descriptive statistics. Baseline value for these PD endpoints is defined to be the average of the last two non-missing values before treatment. A parametric analysis of variance (ANOVA) using a mixed-effectsmodel appropriate for this parallel group design will be fitted to thenatural logarithm transferred actual GFR obtained at Weeks 4, 8, 16,and 24. Geometric mean ratios between each test treatment (ie, STB,ATV/r + FTC/TDF, or EFV/FTC/TAF)

and reference treatment(ie, ATV/r + ABC/3TC) and 90% confidence intervals will beconstructed.A parametric analysis of variance using a mixed-effects modelappropriate for repeated measurements will be fitted to the naturallogarithm transferred aGFR within each treatment. Geometric meanratios between each post baseline visit and baseline visit and90% confidence intervals will be constructed within eachtreatment group.

Documents

Study results

GS-US-236-0140-Synopsis_f-redact.pdf (293.61 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown