An Evaluation of the Safety of Lamivudine in HIV Positive Patients with Renal Impairment (208948)

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Study Finalised

Administrative details

EU PAS number

EUPAS27718

Study ID

40815

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

ViiV Healthcare

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/12/2017

Actual: 14/12/2017

Study start date
Planned: 30/05/2019

Actual: 14/02/2019

Date of final study report
Planned: 30/08/2019

Actual: 18/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ViiV Healthcare

Study protocol

viiv-208948-protocol-redact.pdf (1.36 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

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

Observational cohort analysis

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To estimate the association between 3TC doseprescribed (300 mg vs 150 mg) and the rate of a composite outcome consisting of specific diagnoses of interest and severe laboratory abnormalities among patients with a baseline eGFR between ≥ 30 ml/min/1.73m2 and ≤ 49 ml/min/1.73m2

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

LAMIVUDINE

Medical condition to be studied

Human immunodeficiency virus transmission

Population studied

Short description of the study population

The study sample will be identified from the OPERA Observational Database for analysis per the inclusion/exclusion criteria defined below.

Inclusions:

1) A diagnosis of HIV, a positive HIV Western Blot, or a positive HIV enzymelinked immunosorbent assay (ELISA); and a detectable HIV viral load test

2) At least 13 years of age at the time of 3TC initiation

3) eGFR ≤ 49 ml/min/1.73m2 and ≥ 30 ml/min/1.73m2 at baseline

4) Initiating 3TC for the first time while in the target eGFR range

Exclusions:

1) HIV negative

2) eGFR <30 ml/min/1.73m2 at time of 3TC initiation

3) eGFR >49 ml/min/1.73m2 at time of 3TC initiation

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Immunocompromised

Renal impaired

Estimated number of subjects

15.000

Study design details

Data analysis plan

Descriptive analyses will be conducted for patients prescribed 3TC 150 mg and 300 mg per day. Medians and interquartile ranges for continuous variables will be compared between daily dose groups using Wilcoxon Rank Sum test. Frequencies (counts and percentages) for categorical variables will be compared using Pearson Chi-Square test. The incidence rate of the composite outcome (specific diagnoses of interest and/or laboratory abnormalities of grade 3-4) will be estimated within each dose group and also compared across each of the total daily dosing groups (i.e. 300 mg vs. 150 mg) using univariate Poisson regression (including treatment term only). Multivariable Poisson regression adjusting for retained covariates will be employed to estimate the incidence rate ratio for the composite outcome comparing total 3TC daily doses of 300 mg vs.150 mg, using time since 3TC initiation as the offset. Statistical hypothesis test will be based on the adjusted rate ratio from the final Poisson model

Documents

Study results

viiv-208948-clinical-study-report-redact.pdf (1.36 MB)

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, OPERA Database - Prospectively collected electronic medical record data

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

No