Real-life study of single tablet regimen (STR) and multi tablet regimen (MTR) usage in Germany on persistency of initial therapy - STRingent

First published: 21/03/2014

Last updated: 27/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6118

Study ID

16940

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This non-interventional trial will enroll 1000 patients, who are antiretroviral therapy naive, HIV-1 infected and initiate their first anti HIV treatment. There will be 500 patients in each arm (STR-arm and MTR-arm), each patient shall be documented for 12 months. Main objective is therapy persistency compared between STR and MTR. Additionally the study will collect data on laboratory parameters, adherence, quality of life, and adverse drug reactions.

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

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Institution | Pharmaceutical company

Multiple centres: 41 centers are involved in the study

Contact details

Study institution contact

Gilead Study Director GileadClinicalTrials@gilead.com

Study contact

GileadClinicalTrials@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/02/2014

Actual: 26/02/2014

Study start date

Planned: 30/04/2014

Actual: 19/05/2014

Data analysis start date

Planned: 20/07/2016

Actual: 21/04/2016

Date of final study report

Planned: 21/04/2017

Actual: 08/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences GmbH

Study protocol

protocol GS-DE-236-1272-FINAL-COMPLETE-VERSION 2.pdf (915.66 KB)

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

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

Persistency of initial ART

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate persistency of initial HIV therapy in subjects starting with STR or MTR during the first year of therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AE) Protease inhibitors

Protease inhibitors

(J05AF) Nucleoside and nucleotide reverse transcriptase inhibitors

Nucleoside and nucleotide reverse transcriptase inhibitors

(J05AG) Non-nucleoside reverse transcriptase inhibitors

Non-nucleoside reverse transcriptase inhibitors

(J05AR) Antivirals for treatment of HIV infections, combinations

Antivirals for treatment of HIV infections, combinations

(J05AX) Other antivirals

Other antivirals

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

Antiretroviral therapy naive, HIV-1 infected adult patients in Germany who start their first anti-retroviral therapy either with a single tablet regimen (STR) or multi tablet regimen (MTR).

Age groups

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

Estimated number of subjects

365

Study design details

Outcomes

To evaluate persistency of initial HIV therapy in subjects starting with STR or MTR during the first year of therapy. characteristics of HIV-infected subjects with initial therapy,treatment motivation and the specific treatment regimen (STR or MTR)STR/MTR efficacy regarding HIV-RNA and CD4 cell count changesadherence to ART medicationreasons for treatment discontinuation or change of therapyquality of life and health status (SF36, HIV Symptom Index)adverse drug reactions

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Data analysis plan

We will employ descriptive statistics and multivariable analyses adjusting for relevant confounders and appropriate statistical tests. These include:Binary/categorical/ordinal variables: Frequency distributions using Chi-square tests and Fisher’s exact tests.Continuous variables: Comparison of means (+ 95% CI) using t tests, and comparison of medians (+ IQR) using non-parametric tests.Rates of events by person-time of exposure to either MTR or STR will be computed using Poisson regression, adjusting for confounding variables.

Documents

Study results

GS-DE-236-1272 final report abstract 08Dec2016.pdf (66.37 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

No