Impact of single tablet regimens on adherence and prescription errors? How big an issue and how relevant in both clinical and economic terms (iSTRAP)

First published: 19/12/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS5440

Study ID

19193

DARWIN EU® study

No

Study countries

Italy

Portugal

Spain

United Kingdom

Study description

The aim of this international retrospective study is to evaluate the potential benefits of STR in enhancing adherence, and its clinical and economic consequences in the European context. The study also aims at quantifying prescription errors and identifying those that can be avoided by the use of STRs.

Study status

Finalised

Research institutions and networks

Institutions

INMI "Lazzoro Spallanzani"

Universta di Torino Turin, Hospital Ramón y Cajal Madrid, Hospital Universitario de la Princesa (HULP) Madrid, Hospital del Mar Barcelona, Hospital do Barlavento Algarvio Faro, Centro Hospitalar de Setúbal Setubal, St. Georges Hospital London, Queen Elizabeth Hospital Birmingham, National Institute for Infectious

Diseases 'L. Spallanzani' Rome

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Antinori

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/09/2013

Actual: 09/09/2013

Study start date

Planned: 01/09/2014

Actual: 13/02/2015

Date of final study report

Planned: 02/03/2015

Actual: 07/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gilead Sciences International Ltd

Study protocol

iSTRAP GS-EU-264-1271_final_16May14.pdf (796.14 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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

This study aims to determine whether STRs, as SA-free regimens, will (1)improve adherence and generate clinical and economic benefits (2) prevent prescription errors.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ATRIPLA

EVIPLERA

STRIBILD

Medical condition to be studied

HIV test positive

Population studied

Short description of the study population

HIV-1 infected adult patients who received antiretroviral treatment (ART) between 1st January 2009 and 31st December 2013 for at least 90 days, recruited from centers in Italy, Portugal, Spain and UK by Investigators that have expertise in the management of HIV infection.

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

2215

Study design details

Outcomes

To assess the impact of STRs on adherence in HIV-1 infected patients. 1)Assess the efficacy consequences of NA and OIA, overall and STR versus non-STR (2)Assess the effect of NA and OIA on hospital resource utilization, overall and STR versus non-STR (3)Assess the economic consequences of NA and OIA by cohort (STR versus non-STR) (4)Assess the impact of STR in virological failure, hospitalization and ART plus hospitalization costs (5)Quantify ART prescription

errors

Data analysis plan

Baseline characteristics will be reported using descriptive statistics. In general, when presenting descriptive statistics the following parameters will be presented:(1) for qualitative data: absolute and relative frequencies. Percentages will be based on the total number of subjects with non-missing values unless specified otherwise. Counts for missing values will be also tabulated but missing values will not be considered in the percentages(2) for quantitative data: use of mean, standard deviation, median, 25th and 75th percentiles, minimum and maximum and number of non-missing cases (95% confidence intervals for parameters of interest).

Documents

Study results

CSR SUMMARY-pgs. 4-10_FINAL_GS-EU-264-1271_iSTRAP_20170224.pdf (246.17 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.

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols_27Nov14_signed.pdf (491.08 KB)

Data sources

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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