Assessment of the effectiveness of risk minimisation measures set up for new safety information for Efient® (Prasugrel): a multinational survey among physicians to evaluate their knowledge and consideration of the new safety warning for Prasugrel in four European countries (H7T-MC-B021)

First published: 16/04/2014
Last updated: 29/03/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/15799

EU PAS number
EUPAS6355

Study ID
15799

DARWIN EU® study
No

Study countries
France
Germany
Netherlands
United Kingdom

Study description
The research question is whether the new safety information included in the risk minimisation measures (Direct Healthcare Professional Communication (DHPC), international congress and journal publication) were effective in:• educating Healthcare Professionals (HCPs) about the increased bleeding risk when pre-treating with a loading dose of Efient® (prasugrel) prior to diagnostic coronary angiography in UA/NSTEMI patients, and• influencing their consideration of this risk when prescribing a loading dose of Efient® (prasugrel).

Study status
Finalised

Research institution and networks

Institutions

Real World Evidence Solutions, IMS Health

France
First published: 06/09/2011
Last updated
19/10/2012

Institution
ENCePP partner
Other

Contact details

Study institution contact
Claudia Salinas
Study contact

claudia.salinas@lilly.com
Primary lead investigator
Toussi Massoud
Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:
20/12/2013
Actual:
20/12/2013

Study start date
Planned:
02/06/2014
Actual:
10/06/2014

Data analysis start date
Planned:
05/08/2014
Actual:
19/08/2014

Date of final study report
Planned:
12/12/2014
Actual:
05/01/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company and Daiichi Sankyo Company

Study protocol

B021 RMiP PASS Protocol.pdf(628.84 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 topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:
Primary data collection

Main study objective:
To evaluate the proportion of targeted physicians who are knowledgeable of the new safety warning about Prasugrel.

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Name of medicine, other
Effient

Medical condition to be studied
Acute coronary syndrome

Population studied

Short description of the study population
Physicians, prescribers, or potential prescribers, of Efient® (prasugrel); Specialists of any of those targeted for the Direct Healthcare Professional Communication (DHPC): cardiologists in all countries; physicians working in emergency departments, according to country specificities (cardiologists, emergency physicians, and physicians working in first aid).

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)

Estimated number of subjects
442

Study design details

Outcomes
To evaluate the proportion of targeted physicians who are knowledgeable of the new safety warning about prasugrel. To evaluate whether the physicians will consider the safety warning when prescribing Efient® (prasugrel).

Data analysis plan
The statistical analysis will be conducted using the SAS®softwareV9.3 on Windows™ (SAS Institute, North Carolina, USA).Statistical results of the four countries will be presented in the same report, overall, by country and physician's specialty.Continuous variables will be described by their number (of valid cases, of missing values), mean, standard deviation, median, Q1, Q3, minimum and maximum.Categorical variables will be described as the total number and relative percentage per category. These will be the percentage per category.Confidence intervals of 95% will be calculated, when relevant.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Cross-sectional survey

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