Drug usage patterns of Pylera® in France using the national claims reimbursement database (DUS)

First published: 03/05/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3901

Study ID

50218

DARWIN EU® study

No

Study countries

☐ France

Study description

The objective of the study is to describe the usage patterns of Pylera® in real-life practice. All subjects in the EGB database with one or more claims of Pylera® from April 2013 to March 2015 will be included in the study. A reference population will be defined using patients with a dispensation of specific tritherapy to eradicate H. pylori and the same design. Several cohorts will be identified from Pylera® post-launch, each representing an increment of the number of patients including in the preceding cohort, as well as of the follow-up duration. Consequently, each successive and incremental cohort will be described using information available at the time of data extraction. The index date is defined as the date of the first dispensation of Pylera® (Pylera® population) and as the date of the first dispensation of specific tritherapy to eradicate H. pylori (Reference population). Patients will be included for a period of 2 years and analysed after one month of follow-up (description at inclusion), after 3 months of follow-up (misuse), after one year of follow-up (treatment failure), and after 2 years of follow-up (recurrence). The evaluation criteria will be defined as: - Number of drug packs dispensed per patient and per year - Misuse: dispensation of more than one pack of Pylera® at index date or a dispensation of Pylera® not preceded by urea breath test (UBT) or endoscopy (within the year before first dispensation) - Normal use: patient without misuse at index date - Treatment failure: dispensation of a second pack of Pylera® or of another H. pylori eradication drug combination after or not UBT or endoscopy in the 12 months following first dispensation of Pylera® - Treatment of recurrent infection: dispensation of a new pack of Pylera® or of another drug combination for H. pylori eradication after or not UBT or endoscopy 12 months or more after the last dispensation of Pylera®.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicholas Moore

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/06/2012

Study start date
Actual: 09/10/2013

Date of interim report, if expected
Planned: 30/06/2016

Actual: 28/06/2016

Date of final study report
Planned: 31/05/2017

Actual: 09/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aptalis Pharma

Study protocol

PYLERA-DUS Protocol-V3 1-20130502 clean.pdf(1.09 MB)

PYLERA-DUS Protocol-V6.0 (signed)-20160211 vf.pdf(965.07 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

DE/H/2467/001/DC

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the usage patterns of Pylera® in real-life practice by obtaining the following data: prescribers, patient age, patient gender, dispensed dose and quantity, number of dispensations over the study period, and concomitant medications dispensing (in particular, of all PPIs).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, longitudinal study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A02BD08) bismuth subcitrate, tetracycline and metronidazole

bismuth subcitrate, tetracycline and metronidazole

Population studied

Short description of the study population

The study included subjects with one or more claims of Pylera® in French databases (SNIIRAM and EGB) from the first marketing in France, starting from April 2013 to March 2015. The study also identified several cohorts from Pylera® post-launch, corresponding to patients with a first prescription in the EGB database.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Misuse: dispensation of more than one pack of Pylera at index date or a dispensation of Pylera not preceded by urea breath test (UBT) or endoscopy (within the year before first dispensation) / Normal use / Treatment failure / Treatment of recurrent infection, Concomitant medication, healthcare usage, presence of hospitalisation, duration of treatment as assessed by the number of packs dispensed, each counting for 10 days of treatment, total quantity of bismuth subcitrate dispensed per patient.

Data analysis plan

The statistical analyses will be carried out for each interim report and final report by the Department of Pharmacology according to a documented and approved Statistical Analysis Plan (SAP). The SAP describes the statistical

analyses as foreseen at the time of planning the study. For each report, statistical analysis will be performed after each database extraction from EGB using SAS® software (SAS Institute, last version, North Carolina, USA). Blind double programming will be used for the main outcome measures. Qualitative variables (dichotomous or categorical) will be described in terms of number and frequency. Quantitative variables will be described in terms of mean, standard deviation, median, first and third quartiles. Descriptive statistics of population included in the study, including patient demographics, prescribers, concomitant medication, usage patterns of Pylera® and evolution over time will be carried out.

Documents

Study results

PYLERA-DUS-synthese cohorts 3 5-V1.0 (clean)-20170609.pdf(551.8 KB)

Study publications

Blin P, Rouyer M, Guiard E, Zerbib F, Diquet B, Mégraud F, Tison F, Abouelfath ...

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2013-0016-DoI PBlin-SDPP-3901.pdf(1.2 MB)

conflict NM.pdf(647.8 KB)

Composition of steering group and observers

EUPAS3901-3909.pdf(55.14 KB)

Signed code of conduct

2013-0021-Declaration compliance CoC-SDPP-3142.pdf(343.66 KB)

Signed code of conduct checklist

2013-0021-Checklist CoC-SDPP-3142 (2).pdf(628.08 KB)

Signed checklist for study protocols

2013-0021-Checklist Study Protocols-SDPP-3142 (2).pdf(229.61 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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