A Safety and Pharmacokinetic study in Real-life practice of Pylera® in France: The SAPHARY Study

First published: 20/11/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3142

Study ID

47210

DARWIN EU® study

No

Study countries

☐ France

Study description

The primary objective of the study is to verify the absence of accumulation of bismuth in subjects prescribed Pylera®. The study is a single-arm, open label trial in 200 presumed Helicobacter Pylori-positive subjects and is restricted to centers in France. This study has an anticipated recruitment period of 24 months. Eligible subjects will stay in study for approximately 6 weeks. Following identification of participating general practice and specialist study centers, subjects deemed eligible for study will be identified and may be enrolled. To assess eradication, subjects will complete a diagnostic H. pylori test (breath test, biopsy, or other test at the discretion of the Investigator) following a period of at least 28 days after the end of treatment. Subjects will provide two blood samples for assessment of plasma and whole blood bismuth concentrations, with one sample provided prior to start of Pylera® treatment and one sample provided upon completion of the 10-day treatment with Pylera®. If accumulation of bismuth is detected (defined as whole blood bismuth concentration exceeding 50 µg/L), subjects will be contacted to immediately return to the laboratory to draw a third verification sample and will be referred for potential inclusion and follow-up in a separate intensive monitoring program. In case of a neurological adverse event indicative of bismuth encephalopathy blood samples will be as quickly processed as possible. A diagnostic H. Pylori test to assess H. Pylori eradication should be repeated on one single occasion at least 28 days post-treatment.

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

Gastroenterologists France, General Practitioners France

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick BLIN

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 15/07/2013

Study start date
Actual: 13/03/2014

Data analysis start date
Planned: 01/10/2014

Date of interim report, if expected
Actual: 28/04/2015

Date of final study report
Planned: 31/10/2016

Actual: 25/10/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aptalis Pharma

Study protocol

Ma-PY-HpPK11-01_PYLERA_S_PRO_SAPHARY-RMP_EN 0T-20131104(signé) vf.pdf (1.44 MB)

amended-protocol-pyr-md-301-amendment-6.pdf(1.63 MB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

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

Pharmacokinetic study

Data collection methods:

Primary data collection

Main study objective:

To verify the absence of accumulation of bismuth in subjects prescribed Pylera, a pharmacokinetic approach in a real-life setting

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicenter, open-label, single-arm, clinical trial

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

Patients who have been prescribed Pylera®.

To be eligible, subjects must meet all of the following criteria:

1. Men and women 18 years of age and older who have received a prescription for Pylera® therapy from the Investigator

2. Mental and legal ability to give written Informed Consent and judged by the

Investigator to be capable of following the procedures outlined within the protocol

Subjects with any of the following conditions must be excluded from this study:
1. Women who are pregnant or nursing
2. Any concern by the Investigator regarding the safe participation of the subject in the study or for any other reason the Investigator considers the subject inappropriate for participation in the study

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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

200

Study design details

Outcomes

Post-treatment whole blood and plasma concentration of bismuth (metal) will be described after subtraction of the baseline value for each subject. Individual observed results will also be classified as « above » or « bellow » the threshold of 50 micrograms per liter for whole blood bismuth concentrations. The safety profile will be assessed in terms of overall adverse events, vitals signs, and concomitant medication usage over 10-days treatment period, as well as at the 4 weeks follow-up period after treatment.The eradication rate of Pylera is

defined as the proportion of negative test of diagnostic H. Pylori test conducted at least 28 day following the end of treatment with Pylera.

Data analysis plan

A detailed statistical analysis plan will be performed before database lock using SAS® software. Descriptive statistics including mean, median, standard deviation, minimum, and maximum will be presented for continuous variables. For categorial variables, the number of subjects and percentage within each category will be presented. Bismuth concentrations (Cobs, Cmin) will be described at baseline and at the end of treatment and bismuth accumulation value will be estimated. Proportion of subjects who experienced any/serious adverse events will be assessed, including 95% confidence interval (CI). The eradication rate of Pylera will be calculated from proportion and 95% CI of subjects having negative test of diagnostic H. pylori test at the end of study. An interim analysis of bismuth concentration is planned 18 months after Pylera market launch. No statistical comparisons will be performed.

Documents

Study results

SAPHARY-Abstract of Final study report-v1.0-20161025.pdf(500.23 KB)

Study publications

Guiard E, Lelievre B, Rouyer M, Zerbib F, Diquet B, Mégraud F, Tison F, Bignon ...

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Pylera-SAPHARY-Annex5-DOI NM-20130509.pdf(1.18 MB)

Pylera-SAPHARY-Annex5-DOI-PBL(signé)-20130924.pdf(1.15 MB)

Composition of steering group and observers

EUPAS3142-5208.pdf(55.14 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Laboratory data, Prospective patient-based data collection, Medical charts, clinic charts, nurses' notes, medical correspondence regarding the human subject, subject progress notes, Pathology reports, Study worksheets, Electronic hospital reporting system

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