# 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.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

## Bordeaux PharmacoEpi, University of Bordeaux

France

**First published:** 07/02/2023

**Last updated:** 08/12/2025

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

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**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)

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**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

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.

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