An observational multicenter study on antibiotic resistance of Helicobacter pylori in France (PHARE)

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Study | Finalised

Administrative details

EU PAS number

EUPAS35756

Study ID

35817

DARWIN EU® study

No

Study countries

France

Study description

Observational multicenter study to be conducted in France, with subjects having scheduled one consultation with their gastroenterologist as part of their regular follow up for an endoscopy with biopsies (antral and fundic) to look for infection by Helicobacter pylori and to test the resistance of this bacterium to antibiotics. This study is non-interventional. It is conducted according to the usual medical practice in accordance with the current recommendations and does not impose additional diagnostic approaches or therapeutics strategies.

Study status

Finalised

Research institutions and networks

Institutions

Umanis Clinical Research

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

Francis Mergraud IR-CTRegistration@allergan.com

Study contact

IR-CTRegistration@allergan.com

Primary lead investigator

Francis Mergraud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2013

Actual: 12/02/2013

Study start date

Planned: 28/02/2014

Actual: 24/02/2014

Data analysis start date

Planned: 28/02/2015

Date of interim report, if expected

Planned: 30/04/2015

Actual: 19/06/2015

Date of final study report

Planned: 30/09/2019

Actual: 10/12/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Aptalis

Study protocol

F002343-protocole ENG-5.0 140417_final version avec page de signature 29 May 2020_Redacted.pdf (779.84 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)

Other study registration identification numbers and links

PYR-12-01

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To assess the resistance rate in clinical isolates of Helicobacter pylori to antibiotics(clarithromycin, levofloxacin, tetracycline, rifamycin, amoxicillin and metronidazole).

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Observational multicenter study

Study drug and medical condition

Medical condition to be studied

Helicobacter infection

Population studied

Short description of the study population

The study population was defined as being comprised of patients 18 years of age and older who had a scheduled or planned endoscopy at one of the centers involved in the study, who exhibited a pathology potentially associated with an infection by H. pylori or who had failure of a previous treatment for eradication, and who signed the information consent.

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

Other

Special population of interest, other

Helicobacter pylori infected patients

Estimated number of subjects

3000

Study design details

Outcomes

Resistance rate in clinical isolates of Helicobacter pylori to antibiotics (clarithromycin, levofloxacin, tetracycline, rifamycin, amoxicillin and metronidazole). - Trend in strain resistance over 5-year period following the commercial launch of PYLERA®. - To evaluate the impact of evolution of strain resistance to antibiotics on the efficacy to PYLERA® treatment.

Data analysis plan

The resistance of Helicobacter pylori to six different antibiotics will be determined by agar diffusion using two different tests: disk diffusion for tetracycline, rifampicin (for rifamycin resistance), and levofloxacin, and Epsilometer test (E-tests) for clarithromycin, metronidazole and amoxicillin. Real time PCR for molecular characterization of resistance mutations associated to clarithromycin resistance will be performed on a subset of strains.

Documents

Study results

PYR-12-01 Abstract.pdf (125.06 KB)

Study, other information

PHARE Study Report Abstract (1st Interim Report) 2015.pdf (28.28 KB)

PHARE Study Report Abstract (2nd Interim Report) 2017.pdf (47.72 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.

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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