A Real-World Study Evaluating the Safety of Pantoprazole Sodium IV in Infants Aged 1 Month to <1 Year and Patients Aged 1 to <2 Years Using an Electronic Health Records Database from the United States

First published: 03/02/2022

Last updated: 18/09/2024

Study Finalised

Administrative details

EU PAS number

EUPAS45389

Study ID

46262

DARWIN EU® study

No

Study countries

☐ United States

Study description

Retrospective cohort study using Optum’s longitudinal electronic health records (EHR) repository from the United States (US). Two separate cohorts, ie, infants aged 1 month to <1 year and patients aged 1 to <2 years who received at least one dispensing of IV pantoprazole during a study period of 01 January 2007 to 31 December 2020 and those enrolled in the database for at least 30 days prior to the date of first dispensing of IV pantoprazole will be identified from the Optum’s longitudinal EHR repository. Within each cohort, 3 subgroups will be identified: (1) patients with ICD-9-CM or ICD-10-CM codes for GERD with EE, (2) patients with ICD-9-CM or ICD-10-CM codes for GERD but without EE, and (3) patients without diagnosis codes for GERD or EE. The research question for this study is: What are the incidence rates of potential safety events of interest in infants aged 1 month to <1 year and in patients aged 1 to <2 years who were treated with IV pantoprazole in the real-world setting? Exposure to IV pantoprazole will be identified from inpatient procedure and drug codes including National Drug Codes (NDC) and Healthcare Common Procedure Coding System (HCPCS) codes. Optum’s longitudinal EHR repository from the US will be used for this study. This dataset contains a combination of structured data (e.g. diagnoses, procedures, prescriptions) and information from unstructured data (e.g. drug rationale, provider notes) from the electronic health record and corresponding claims information for those instances. The claims are verified, adjudicated, adjusted, and de-identified. The database currently encompasses the claims and EHR data of more than 95 million patients with approximately 1.9 million patients aged less than 2 years from 01 January 2007 through 31 December 2020.

Study status

Finalised

Research institutions and networks

Institutions

Aetion

Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gandhi Sampada

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/05/2021

Actual: 27/05/2021

Study start date
Planned: 04/02/2022

Actual: 04/02/2022

Date of final study report
Planned: 30/06/2022

Actual: 23/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

B1791096_PROTONIX PASS PROTOCOL FINAL_12 AUG 2021.pdf(486.15 KB)

Protonix PASS B1791096 Protocol Amendment 1 Clean 02-10-22.pdf(847 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

What are the incidence rates of potential safety events of interest in infants aged 1 month to <1 year and in patients aged 1 to <2 years who were treated with IV pantoprazole in the real-world setting?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A02BC02) pantoprazole

pantoprazole

Population studied

Age groups

Infants and toddlers (28 days – 23 months)

Estimated number of subjects

14146

Study design details

Outcomes

The incidence of prespecified outcomes of interest as specified in the protocol in patients with a diagnosis of GERD with or without EE and treated with IV pantoprazole.

Data analysis plan

All statistical analyses will be performed in the two cohorts of interest: infants aged 1 month to <1 year and patients aged 1 to <2 years. Descriptive statistics will be presented to characterize the overall cohort treated with IV pantoprazole and the 3 subgroups defined based on the presence or absence of GERD and EE during the baseline period or on the index date. Incidence rates of outcomes of interest will be estimated as the number of patients with a specific outcome of interest during the follow-up period divided by the total person-time at risk and reported as incidence rate per 1,000 person-years with associated 95% confidence intervals. Incidence rates for all outcomes of interest will be calculated in the overall cohort and in each of the 3 subgroups. Within the overall cohort and in the 3 subgroups, incidence rates will be estimated by duration of IV pantoprazole treatment (<4 days, ≥ 4 days). Two sensitivity analyses will be performed.

Documents

Study report

B1791096 Non-Interventional Study Report Manuscript Signatures 23-Jun-2022.pdf(1.16 MB)

B1791096 SAP Protonix PASS_V5_01-24-2022_.pdf(2.76 MB)

Protonix PASS B1791096 Non-Interventional Study Report Abstract 23-Jun-2022_FINAL (1).pdf(2.45 MB)

Protonix PASS B1791096 Protocol Amendment 1 Clean 02-10-22.pdf(404.12 KB)

Protonix PASS B1791096_Report_23-Jun-2022_FINAL.pdf(13.21 MB)

Data management

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 source(s), other

Optum EHR with Integrated Claims United States

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