DARWIN EU® Drug utilisation study of medicines with prokinetic properties in children and adults diagnosed with gastroparesis

First published: 16/10/2023
Last updated: 13/05/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/107280

EU PAS number
EUPAS106798

Study ID
107280

DARWIN EU® study
Yes

Study countries
Belgium
France
Germany
Netherlands
Spain
United Kingdom

Study description
Gastroparesis is a medical condition characterized by delayed gastric emptying, causing symptoms like postprandial fullness, nausea, vomiting, and upper abdominal pain. It affects individuals across different age groups, encompassing both paediatric population and

adults. Pharmacotherapy, particularly medication with prokinetic properties, has been used to manage symptoms, which includes off-label use. The European Medicines Agency commissioned this DARWIN EU© CC study to: describe the characteristics of children and adults prescribed medications with prokinetic properties stratified by indication of use (gastroparesis), to determine the dose, formulation, cumulative duration and setting at time of treatment initiation of any of the prokinetic drugs of interest for patients diagnosed with gastroparesis, in children and adults separately, and to determine the incidence and prevalence of use of medications with prokinetics properties for patients diagnosed with gastroparesis, in the paediatric population and in adults separately, stratified by calendar year, age categories, sex and database during the study period between 2012 and 2022.

Study status
Finalised

Research institution and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

Belgium
Croatia
Denmark
Estonia
Finland
France
Germany

Hungary
Netherlands
Norway
Portugal
Spain
United Kingdom
First published: 01/02/2024
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Network

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
20/06/2023
Actual:
20/06/2023

Study start date
Planned:
01/01/2012
Actual:
01/01/2023

Date of interim report, if expected
Planned:
17/11/2023

Date of final study report
Planned:

29/12/2023
Actual:
15/12/2023

Sources of funding

- EMA

Study protocol

Study Protocol P2 C1-005 Version 4.1 final.pdf(870.37 KB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Study design:
- New drug user cohort study
- Population-level cohort study

Main study objective:
The main objective of the study is to determine the dose, formulation, cumulative duration and setting at time of treatment initiation of any of the prokinetic drugs of interest for patients diagnosed with gastroparesis and to determine the incidence and prevalence of

use of medications with prokinetics properties in patients diagnosed with gastroparesis, in children and adults separately.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
- Cisapride
- Clebopride
- Itopride
- Cinitapride

Study drug International non-proprietary name (INN) or common name
DOMPERIDONE
ERYTHROMYCIN
METOCLOPRAMIDE

Anatomical Therapeutic Chemical (ATC) code
(A03FA01) metoclopramide
(A03FA02) cisapride
(A03FA03) domperidone
(A03FA06) clebopride
(A03FA07) itopride
(A03FA08) cinitapride
(J01FA01) erythromycin

Medical condition to be studied
Diabetic gastroparesis
Dyspepsia
Irritable bowel syndrome
Vomiting
Diabetes mellitus
Hypothyroidism
Scleroderma
Parkinson's disease
Multiple sclerosis
Gastroptosis

Additional medical condition(s)
Gastroparesis syndrome, Gastroesophageal reflux disease, Chronic constipation, Systemic Lupus Erythematous, Ehlers Danlos Syndrome, Acute migraine, Cerebrovascular disease

Population studied

Age groups
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)

Estimated number of subjects
2000000

Study design details

Data analysis plan
Patient-level drug utilization: Large-scale patient-level characterization will be conducted at index date including patient demographics, comorbidity and medication. Cumulative duration of use of medication with prokinetic properties, dose, formulation and different types of setting will be reported. Population-level utilization of medication with prokinetic properties: Annual period prevalence of the use of medications with prokinetics properties and annual incidence rates per 100000 person years will be estimated. For all analyses a minimum cell count of 5 will be used when reporting results, with any smaller counts obscured.

Data management

Data sources

Data source(s)
IPCI
The Information System for Research in Primary Care (SIDIAP)
Clinical Practice Research Datalink (CPRD) GOLD
Disease Analyzer Germany

Longitudinal Patient Data - Belgium
Institut Municipal d'Assistència Sanitària Information System
Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)
Electronic healthcare records (EHR)
Other

Use of a Common Data Model (CDM)

CDM mapping
Yes

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No