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

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Last updated: 11/07/2024

Study Finalised

Administrative details

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 institutions 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: 23/05/2025

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
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands

- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] 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

Katia Verhamme

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

metoclopramide

(A03FA02) cisapride

cisapride

(A03FA03) domperidone

domperidone

(A03FA06) clebopride

clebopride

(A03FA07) itopride

itopride

(A03FA08) cinitapride

cinitapride

(J01FA01) erythromycin

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.

Documents

Study report

DARWIN EU_D2.2.4_Report_ P2-C1-005_Prokinetic drugs_v2.1.pdf(3.37 MB)

Data management

Data sources

Data source(s)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

IQVIA Disease Analyzer Germany

IQVIA 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

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No