

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

**First published:** 16/10/2023

**Last updated:** 11/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS106798

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### Study ID

107280

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### DARWIN EU® study

Yes

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### Study countries

Belgium

France

Germany

- Netherlands
  - Spain
  - United Kingdom
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### **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.

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### **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

**Last updated:** 30/04/2025

Network

## Contact details

### Study institution contact

Ilse Schuemie [study@darwin-eu.org](mailto:study@darwin-eu.org)

Study contact

[study@darwin-eu.org](mailto:study@darwin-eu.org)

### Primary lead investigator

Katia Verhamme

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 20/06/2023

Actual: 20/06/2023

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**Study start date**

Planned: 01/01/2012

Actual: 01/01/2023

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**Date of interim report, if expected**

Planned: 17/11/2023

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**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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

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**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

**Medicinal product name, other**

- Cisapride
  - Clebopride
  - Itopride
  - Cinitapride
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**Study drug International non-proprietary name (INN) or common name**

DOMPERIDONE

ERYTHROMYCIN

METOCLOPRAMIDE

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**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

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**Medical condition to be studied**

Diabetic gastroparesis

Dyspepsia

Irritable bowel syndrome

Vomiting

Diabetes mellitus

Hypothyroidism

Scleroderma

Parkinson's disease

Multiple sclerosis

Gastroptosis

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### **Additional medical condition(s)**

Gastroparesis syndrome, Gastroesophageal reflux disease, Chronic constipation, Systemic Lupus Erythematosus, 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)
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### **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

### 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 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 / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

Clinical Data Warehouse of the Bordeaux University Hospital

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

Yes

### **CDM Mappings**

#### **CDM name**

OMOP

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#### **CDM website**

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

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## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No