Linaclotide Safety Study for the Assessment of Diarrhoea—Complications and Associated Risk Factors in Selected European Populations with IBS-C

First published: 20/09/2016

Last updated: 15/07/2025

Study Finalised

Administrative details

EU PAS number

EUPAS15353

Study ID

40556

DARWIN EU® study

No

Study countries

Spain

Sweden

United Kingdom

Study description

This study is planned to assess the safety of linaclotide in terms of the risk of severe complications of diarrhoea (SCD) during treatment and other risk factors among patients with Irritable bowel syndrome (IBS) predominantly with constipation (IBS-C). Linaclotide is the first medicine authorised for the symptomatic treatment of IBS in the European Union.

Study status

Finalised

Research institutions and networks

Institutions

PPD Evidera

Sweden

United Kingdom

United States

First published: 20/11/2013

Last updated: 22/09/2025

Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Javier Cid

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/08/2016

Study start date

Planned: 13/05/2013

Actual: 13/05/2013

Data analysis start date
Planned: 16/04/2018

Date of final study report
Planned: 30/09/2024

Actual: 25/05/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

P21-481-Protocol v13.1_abstract_Redacted (1).pdf (430.95 KB)

P21-481_Protocol v13.3_Redacted.pdf (2.54 MB)

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

EVM-18888,CMO-EPI-GI-0566

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

-To estimate the risk (case-control OR) of SCD (case) among patients with IBS-C (source population) who received linaclotide prescription vs those who did not, controlling for other potential SCD risk factors (socio-demographics, comorbidities, co-medications and other potential variables of interest) -To describe the crude incidence of diarrhoea among patients with IBS-C (source population)

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

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

LINACLOTIDE

Medical condition to be studied

Irritable bowel syndrome

Diarrhoea

Population studied

Age groups

- 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

200

Study design details

Outcomes

SCD cases are suffering diarrhoea and subsequently any of following: -Dehydration that requires intravenous or oral rehydration with solutions of electrolytes -Electrolyte imbalance -Oliguria -Anuria -New-onset thromboembolism episodes, orthostatic hypotension, syncope, dizziness or vertigo -Acute renal failure -Hypovolaemic shock -Hospitalisation due to diarrhoea -Stupor -Coma -Death

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Data analysis plan

Patient characteristics at the IBS-C cohort entry date will be described for the full cohort of patients with IBS-C by reviewing data for a minimum of 12 months prior. Characteristics at index date will be described for the cases and controls by reviewing data for a minimum of 12 months prior to index date. The crude incidence of diarrhoea and the crude incidence of SCD will be described in: the full cohort of patients with IBS-C, the sub-cohorts of patients with prescriptions of linaclotide and for those groups of patients with increased risk of SCD (patients ≥65 yrs and patients with hypertension, diabetes, or cardiovascular disease diagnostic codes). If the validation results of cases and controls are satisfactory then information from the whole cohort would be used to estimate relative risks of SCD and the exposures of interest (linaclotide) using the Cox proportional hazard model. Otherwise only the nested case-control analysis will be conducted (conditional logistic regression).

Documents

Study report

P21-481_CSR Abstract_Redacted.pdf (321.19 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 source(s)

Clinical Practice Research Datalink

Sweden National Prescribed Drugs Register / Läkemedelsregistret

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

Swedish National Patient Register Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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