

# Linaclootide 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

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### Study ID

40556

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### DARWIN EU® study

No

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### Study countries

 Spain

 Sweden

 United Kingdom

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## 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.

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## 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**

[CT.Disclosures@abbvie.com](mailto:CT.Disclosures@abbvie.com)

### Primary lead investigator

Javier Cid

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 25/08/2016

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### Study start date

Planned: 13/05/2013

Actual: 13/05/2013

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**Data analysis start date**

Planned: 16/04/2018

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**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

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**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

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**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

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### **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)
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### **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  $\geq 65$  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)

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### Data source(s), other

Swedish National Patient Register Sweden

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### 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

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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