Linaclotide Utilisation Study in Selected European Populations

First published: 17/03/2016

Last updated: 10/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12839

Study ID

34073

DARWIN EU® study

No

Study countries

- ☐ Spain
- ☐ Sweden
- ☐ United Kingdom

Study description

This study plans to describe the characteristics of patients newly prescribed linaclotide, especially in certain population subgroups for which the use of linaclotide was not sufficiently documented in the clinical programme (including the elderly, males, pregnant or breast-feeding women, and patients with specific comorbidities or taking other medications), and in groups with potential off-label use and patients with potential for abuse/excessive use. Linaclotide treatment patterns will be also described.

Study status

Finalised

Research institutions and networks

Institutions

Evidera

United Kingdom

First published: 20/11/2013

Last updated: 07/03/2024

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: 27/03/2015

Study start date

Actual: 13/05/2013

Data analysis start date
Planned: 08/05/2017

Actual: 01/08/2018

Date of final study report
Planned: 31/12/2018

Actual: 30/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Linaclotide_DUS_protocol_v4.2_26Jan17_Final_Redacted.pdf(483.29 KB)

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-13108CMO-EPI-GI-0567

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe linaclotide utilisation among patients from three selected European countries: UK, Spain, and Sweden.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LINACLOTIDE

Population studied

Short description of the study population

New users of linaclotide with at least 12 months of previous enrolment in the database (baseline period) before the date of first prescription or dispensation of linaclotide (index date) from three different countries: the UK, Spain, and Sweden.

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)

Special population of interest

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

9650

Study design details

Outcomes

Linaclotide treatment discontinuation and linaclotide treatment switching.

Data analysis plan

Baseline analyses will be conducted to characterise linaclotide users, and socio-demographic and clinical variables will be described for all users and for those subgroups of patients who were not sufficiently documented in the clinical development programme. Linaclotide treatment patterns will be described from index date to end of study period for linaclotide utilisation. Kaplan-Meier estimates will be used to describe time to discontinuation in the prescription or dispensation of linaclotide, and to describe switching from linaclotide to another drug used in IBS-C. To better assess differences in time to event by the alleged reason for linaclotide prescription (IBS-C or other condition), Cox regression analysis will be employed if the proportional hazards assumption holds, if not, more complex models will be proposed, including predictor variable interactions with time.

Documents

Study results

EVM-13108_Linaclotide_DUS_Final Report Abstract.pdf(43.97 KB)

Data management

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)

Drug dispensing/prescription data

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