TED-R13-002: A Prospective, Multi-center Registry for Patients with Short Bowel Syndrome (TED-R13-002: SBS Registry)

First published: 26/01/2015

Last updated: 12/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS7973

Study ID

49834

DARWIN EU® study

No

Study countries

- Argentina
- Australia
- Canada
- Croatia

Czechia
Denmark
Finland
France
Germany
Italy
Norway
Slovenia
Spain
Sweden
United Kingdom
United States

Study description

This is a single-group, prospective, observational, multi-center (ie, world-wide) registry designed to collect data on long-term safety and clinical outcomes in Short Bowel Syndrome (SBS) patients.

This registry permits interested SBS patients and SBS-treating health care providers to participate. Patients exposed and not exposed to teduglutide will be recruited. A select set of data will be collected at baseline, and as available, every 6 months (i.e., 2 times a year).

This study is planned for 5 years of enrollment with at least 10 years of follow-up for each SBS patient.

The primary objective of this registry is to evaluate the long-term safety profile for patients with SBS who are treated with teduglutide in a routine clinical setting.

The primary safety outcome is the occurrence of colorectal cancer in SBS patients with any remnant colon currently being treated with or ever having been treated with teduglutide.

The overall observed incidence of colorectal cancer for teduglutide-treated

patients with any remnant colon will be compared with the incidence of colorectal cancer in the latest available US and global cancer data sources (for example, population-based registries, healthcare claims databases, or federated electronic health record networks with validated oncology outcomes). The secondary objective of this registry is to evaluate long-term outcomes in patients with SBS.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 22/10/2013

Study start date
Actual: 23/06/2014

Date of final study report
Planned: 30/04/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

TED-R13-002_Protocol_V2 0_11March2014_redacted.pdf (2.14 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

NCT01990040

https://clinicaltrials.gov/ct2/show/NCT01990040?term=NCT01990040&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate the long-term safety profile for patients with SBS who are treated with teduglutide in a routine clinical setting.
The primary safety outcome is the occurrence of colorectal cancer in SBS patients with any remnant colon currently being treated or ever having been treated with teduglutide.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational Registry

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A16AX08) teduglutide

teduglutide

Medical condition to be studied

Short-bowel syndrome

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1806

Study design details

Outcomes

Occurrence of colorectal cancer in patients with SBS with any remnant colon currently being treated with or ever having been treated with teduglutide. Occurrence of: Other malignancy, Benign neoplasia of GI tract, hepatobiliary system, and pancreas, Colorectal polyps, Intestinal obstruction, Pancreatic and

biliary disease, Heart failure/other manifestations of volume overload, Allergic/hypersensitivity reaction to teduglutide, Other adverse events potentially related to treatment with teduglutide, Change in parenteral support.

Data analysis plan

Detailed statistical analysis methods will be conducted as described in the SAP for this study.

Data will be summarized with tabulated descriptive statistics: number of observations, minimum, maximum, mean, median, standard deviation, and range for continuous variables and counts and percentages for categorical variables.

In addition, graphical data displays will be used to summarize selected data. Person-years of follow-up and incidence rates of selected prospective events will be calculated.

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 sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection. US and global cancer data sources (for example, population-based registries, healthcare claims databases, or federated electronic health record networks with validated oncology outcomes).

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