Open label, multinational, multicentre, prospective, real world observational study of Naloxegol for patients with cancer pain diagnosed with Opioid Induced Constipation (OIC). (NACASY)

First published: 16/04/2018

Last updated: 06/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23610

Study ID

33677

DARWIN EU® study

No

Study countries

Denmark

Finland

France
Germany
Italy
Netherlands
Spain
Sweden
United Kingdom

Study description

Opioids have been the cornerstone of analgesic treatment for severe chronic pain. Opioid Induced Constipation(OIC) is the most commonly reported adverse effect associated with opioids, and compromises patient satisfaction with analgesic treatment, adherence to analgesic treatment regimens and quality of life. Guidelines recommend laxatives for the management of OIC in patients with cancer. In patients who do not respond to standard laxatives, peripherally acting muopioids receptor antagonists (PAMORAs) are a valid option. Naloxegol is an oral PAMORA indicated for the treatment of OIC in adult patients who have had an inadequate response to standard laxatives. No study results evaluating the use of Naloxegol in cancer patients according to routine clinical practice outside of controlled clinical trials are yet available. This study aims to evaluate the safety and efficacy of Naloxegol in a real-world treatment study in patients with cancer pain diagnosed with OIC.

Study status

Finalised

Research institutions and networks

Institutions

Kiowa Kirin International

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

KYRIAKI MYSTAKIDOU

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/09/2018

Actual: 13/09/2018

Study start date

Planned: 31/07/2018

Actual: 14/08/2018

Data analysis start date
Planned: 14/05/2020

Actual: 03/11/2020

Date of interim report, if expected
Actual: 28/01/2020

Date of final study report
Planned: 06/07/2020

Actual: 06/05/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Kyowa Kirin International plc.

Study protocol

KYO229007 (NACASY)_protocol_VF 2.pdf (372.78 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

Incidence of adverse events leading to study discontinuation and response rate during the 4 weeks treatment period.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A06AH03) naloxegol

naloxegol

Medical condition to be studied

Post procedural constipation

Population studied

Age groups

- 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

315

Study design details

Outcomes

Adverse events leading to study discontinuation and rate during the 4 weeks treatment period. Patients that have a BFI score changes Time to the first post-dose bowel movement. Change in stool consistency (Bristol stool scale). Change in Patient Assessment of Constipation (PAC-QOL) Incidence of overall adverse events and SAEs. Analgesic treatment interruptions/dose adjustments. Naloxegol treatment interruptions/dose adjustments. Patient satisfaction (PGI-I).

Data analysis plan

The primary safety end point is the incidence of adverse events leading to study discontinuation. Number and percentage of patients who present an adverse event leading to study discontinuation and 95% CI will be provided. The primary efficacy end point is response rate during the 4 weeks treatment period. Response is defined as three or more bowel movements (without the use of rescue laxative treatment in the previous 24 hours) per week and an increase of one or more bowel movements over baseline. Response rate will be provided as frequency and 95% CI will also be presented. Exploratory and descriptive methods will be used to describe every study variable. Continuous

variables will be described by mean, median, standard deviation, minimum and maximum. Categorical variables will be shown as distribution of frequencies and percentage.

Documents

Study results

KYO0229007(NACASY)_Final Statistical Report_VF1.0_20210506_FullyExecuted.pdf (2.08 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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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