NACASY - (dernière mise à jour : 28/06/2019)

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Informations générales

Titre de l'étude : Real World Observational Study of Naloxegol for Patients With Cancer Pain Diagnosed With Opioid Induced Constipation.

Traitement :

Type d'étude : Qualité de vie / Observationnelle

Phase : NA **Stade** : Localisé à Métastatique **Ligne(s)** : 1, 2, 3, 4, X

Schéma : This is a single-arm, open label, multinational, multicentre, prospective, real world observational study of Naloxegol in adult subjects with Opioid Induced Constipation (OIC) in patients receiving Naloxegol in routine clinical practice. Subjects who are receiving Naloxegol (prescribed by their physician according to the SmPC, which recommends that all currently used maintenance laxative therapy should be halted) during the enrolment period may be eligible for enrolment into the study.

The objective of this study is to assess the safety and efficacy of Naloxegol in a real world setting in cancer patients.

The primary safety end point is the incidence of adverse events leading to study discontinuation.

The primary efficacy end point is the response rate assessed in the 4 week observation 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.

Spécialités / Localisations

Spécialité n°1 : Toutes tumeurs solides

CIM10 - Localisation n°1 : **C** - Toutes localisations

Critères

Critères d'inclusion : - Patient >= 18 years old
- Patient who is receiving treatment with opioids for at least 4 weeks, and is expected to remain on opioids for duration of study
- Patient with opioid-induced constipation
- Patient in whom the clinician plans treatment with Naloxegol according to routine clinical practice (Naloxegol SmPC recommends that all currently used maintenance laxative therapy should be halted)
- Signing of the informed consent

Critères de non-inclusion : Patients with colorectal cancer

Informations promoteur

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Ouverture de l'essai : OUVERT

Liens utiles

ClinicalTrials.gov (anglais) : https://clinicaltrials.gov/ct2/show/NCT03638440