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A Study Evaluating Lanreotide as Maintenance Therapy in Patients With Non-Resectable Duodeno-Pancreatic Neuroendocrine Tumors (REMINET)

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified September 2014 by Federation Francophone de Cancerologie Digestive

Sponsor:

Federation Francophone de Cancerologie Digestive

Information provided by (Responsible Party):

Federation Francophone de Cancerologie Digestive

ClinicalTrials.gov Identifier:

NCT02288377

First received: September 23, 2014

Last updated: November 10, 2014

Last verified: September 2014

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Purpose

This European, prospective, multicentre, double-blind randomised study will evaluate the effect of lanreotide (120 mg every 28 days until disease progression) versus placebo in patients with metastatic/locally advanced, non-resectable, duodeno-pancreatic neuroendocrine tumours.

Condition	Intervention	Phase
Metastatic/Locally Advanced, Non-resectable, Duodeno-pancreatic Neuroendocrine Tumours	Drug: lanreotide	Phase 2 Phase 3

Study Type: [Interventional](#)Study Design: [Allocation: Randomized](#)[Endpoint Classification: Efficacy Study](#)[Intervention Model: Parallel Assignment](#)[Masking: Double Blind \(Subject, Caregiver, Investigator, Outcomes Assessor\)](#)[Primary Purpose: Treatment](#)

Official Title: A EUROPEAN, MULTICENTRE, PHASE II/III RANDOMISED DOUBLE-BLIND, PLACEBO CONTROLLED STUDY EVALUATING LANREOTIDE AS MAINTENANCE THERAPY IN PATIENTS WITH NON-RESECTABLE DUODENO-PANCREATIC NEUROENDOCRINE TUMOURS AFTER FIRST-LINE TREATMENT

Resource links provided by NLM:[MedlinePlus](#) related topics: [Cancer](#) [Carcinoid Tumors](#)[Drug Information](#) available for: [Lanreotide](#) [Lanreotide acetate](#)[Genetic and Rare Diseases Information Center](#) resources: [APUDoma](#) [Carcinoid Tumor](#) [Neuroepithelioma](#) [Pancreatic Cancer](#)[U.S. FDA Resources](#)**Further study details as provided by Federation Francophone de Cancerologie Digestive:**

Primary Outcome Measures:

- Rate of patients alive and progression free at 6 months [Time Frame: estimated 6 months after the last patient is randomized]
[Designated as safety issue: No]
To evaluate the rate of patients alive and progression free at 6 months, assessed by the investigator according to RECIST criteria (version 1.1)

Secondary Outcome Measures:

- Rate of patients alive and progression free at 12 months [Time Frame: estimated 12 months after the last patient is randomized]
[Designated as safety issue: No]
To evaluate the rate of patients alive and progression free at 12 months, assessed by the investigator according to RECIST criteria (version 1.1)
- Safety [Time Frame: estimated 6 months after the last patient is randomized] [Designated as safety issue: Yes]
Safety: the toxicities will be described using the NCI-CTC AE version 4.0

Estimated Enrollment: 222

Study Start Date: September 2014

Estimated Study Completion Date: January 2024

Estimated Primary Completion Date: June 2017 (Final data collection date for primary outcome measure)

[Arms](#)[Assigned Interventions](#)

Experimental: lanreotide In this arm, patients will receive lanreotide 120 mg every 28 days until disease progression	Drug: lanreotide Patients will receive lanreotide 120 mg every 28 days until disease progression
Placebo Comparator: placebo In this arm, patients will receive placebo every 28 days until disease progression	

Detailed Description:

This is a European, prospective, multicentre, double-blind randomised study evaluating lanreotide (120 mg every 28 days until disease progression) versus placebo in patients with metastatic/locally advanced, non-resectable, duodeno-pancreatic neuroendocrine tumours.

Depending on the phase II results, the study may be continued into phase III. The treatment and follow-up of patients will be the same in phase II and phase III. After the first-line treatment, patients will be randomly assigned with a 1:1 ratio to receive either lanreotide or placebo. The study treatment should be initiated within 6 weeks following the confirmation date of stable disease or objective response.

Treatment period:

For each patient, the investigational products (lanreotide or placebo) will be provided according to a double-blind procedure until disease progression or toxicity, in accordance with the protocol.

The estimated average treatment duration for all patients is 12 months.

Follow-up period:

To evaluate overall survival, patients in phase II will have a minimum follow-up period of 12 months; if the study continues to phase III, these patients will have a maximum follow-up period of 10 years. Phase III patients will have a minimum follow-up period of 5 years.

Eligibility

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria**Inclusion Criteria:**

- Metastatic (synchronous or metachronous) or locally advanced, non-resectable, well-differentiated duodeno-pancreatic neuroendocrine tumour, of grade 1 or 2 (WHO 2010 classification; Ki-67 ≤ 20%)
- Progressive before first-line treatment
- Histologically confirmed (either on primary tumour or metastases)
- Pathological diagnosis validated by the NET consulting pathologist
- Documented stable disease or objective response after first-line treatment, within 4 weeks (28 days) prior to randomisation
- The first-line treatment will consist of either a chemotherapy or biotherapy (everolimus or sunitinib) as referred to TNCD or ENETS guidelines. Treatment must have been administered for 3 to 6 months for chemotherapy and for 6 months for biotherapy
- Non-functional tumour or gastrinoma controlled by PPIs
- Age > or = 18 years
- WHO 0, 1 or 2
- Effective contraception for male or female patients of childbearing age, defined as: oral contraceptives, intra-uterine devices, barrier contraceptive methods along with a spermicide gel, or surgical sterilisation. Female patients should use this contraception throughout the treatment period and for 6 months after the last treatment administration. Male patients should use contraception throughout the treatment period and for 3 months after the last treatment administration.
- Signed informed consent prior to initiation of any study-specific procedures or treatment.

Exclusion Criteria:

- History of haematological malignancy or other cancer, except those treated for more than 5 years and considered as cured, carcinoma in situ of the cervix and treated skin cancer (excluding melanoma)
- Poorly differentiated neuroendocrine carcinoma or NET grade 3 ENETS (Ki-67 > 20%)
- If primary resected, bone metastasis exclusively
- Pre-treatment by somatostatin long-acting analogue
- Total bilirubin ≥ 60 µmol/L
- Uncontrolled diabetes
- Contraindication to product used in the study or its components
- Tumour arising in the context of a genetic disease
- Pregnancy or lactation
- Patients unable to undergo medical follow-up due to geographical, social, psychological or legal reasons
- Concomitant participation in another clinical trial investigating a treatment during the treatment phase and within 30 days prior to the start of the study treatment.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02288377

Contacts

Contact: Martina Schneider +33 3 80 39 34 83 martina.schneider@u-bourgogne.fr

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Locations**France**

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Recruiting**Sponsors and Collaborators**

Federation Francophone de Cancerologie Digestive

More Information

No publications provided

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ClinicalTrials.gov Identifier: [NCT02288377](#) [History of Changes](#)
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Health Authority: France: ANSM - Agence Nationale de Sécurité du Médicament (Saint-Denis)

Keywords provided by Federation Francophone de Cancerologie Digestive:

Lanreotide
Duodeno-pancreatic neuroendocrine tumours
Maintenance treatment

Additional relevant MeSH terms:

Adenoma, Islet Cell	Neoplasms by Site
Apudoma	Neoplasms, Germ Cell and Embryonal
Carcinoid Tumor	Neoplasms, Glandular and Epithelial
Neuroendocrine Tumors	Neoplasms, Nerve Tissue
Adenocarcinoma	Neuroectodermal Tumors
Adenoma	Pancreatic Diseases
Carcinoma	Pancreatic Neoplasms
Digestive System Diseases	Angiopeptin
Digestive System Neoplasms	Lanreotide
Endocrine Gland Neoplasms	Antineoplastic Agents
Endocrine System Diseases	Cardiovascular Agents
Neoplasms	Pharmacologic Actions
Neoplasms by Histologic Type	Therapeutic Uses

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