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Efficacy and Safety of Everolimus and (STZ-5FU) Given One Upfront the Other Upon Progression in Advanced pNET (SEQTOR)

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

Verified June 2015 by Grupo Espanol de Tumores Neuroendocrinos

Sponsor:
Grupo Espanol de Tumores Neuroendocrinos

Collaborators:
European Neuroendocrine Tumor Society
Kantar Health
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Grupo Espanol de Tumores Neuroendocrinos

ClinicalTrials.gov Identifier:
NCT02246127

First received: August 20, 2014
Last updated: June 23, 2015
Last verified: June 2015
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to elucidate which sequence of streptozotocin (STZ) based chemotherapy and the mammalian Target of Rapamycin (mTOR) inhibitor, everolimus, gives better results in terms of second Progression Free Survival (PFS) in well differentiated and advanced pancreatic NETs.

Condition	Intervention	Phase
Pancreatic Neuroendocrine Tumours.	Drug: Drug: Everolimus Drug: STZ-5FU	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Crossover Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Randomized Open Label Study to Compare the Efficacy and Safety of Everolimus Followed by Chemotherapy With Streptozotocin-Fluorouracilo (STZ-5FU) Upon Progression or the Reverse Sequence, in Advanced Progressive Pancreatic NETs (pNETs)

Resource links provided by NLM:

Drug Information available for: Fluorouracil Sirolimus Everolimus Temsirolimus

Genetic and Rare Diseases Information Center resources: APUDoma Carcinoid Tumor Neuroepithelioma Pancreatic Cancer

U.S. FDA Resources

Further study details as provided by Grupo Espanol de Tumores Neuroendocrinos:

Primary Outcome Measures:

- Second Progression Free Survival (second PFS) [Time Frame: Up to 84 weeks] [Designated as safety issue: No]
  PFS of Course 1 (PFS1) + interval between treatments + PFS of Course 2 (PFS2), where PFS1 represents progression free survival of Course 1 and PFS2 represents progression free survival of Course 2

Secondary Outcome Measures:

- Adverse events [Time Frame: up to 30 days after 84 weeks] [Designated as safety issue: Yes]
  Number of adverse events, dose reductions, and total dose administered of each treatment.
- Time to first progression [Time Frame: Up to 44 weeks to everolimus and up 40 weeks for STZ-5-FU.] [Designated as safety issue: No]
  Time from the date of randomization to the date of first disease progression.
- Ratio of incremental cost-efficacy (ICER) [Time Frame: Up to 84 weeks.] [Designated as safety issue: No]
  Ratio of the difference of costs incurred on by each treatment arm and the difference of second progression free survival at each arm.
- Response Rate (RR) [Time Frame: Baseline and every 12 weeks up to 84 weeks] [Designated as safety issue: No]
  Rate of objective response (= Complete response (CR)+ Partial Response (PR)+Stable Disease (SD)) measured by RECIST criteria version 1.0

- Early Biochemical response [Time Frame: Baseline and up to 4 weeks] [Designated as safety issue: No]
  Levels of Chromogranin A (CgA)

- Time to second progression [Time Frame: Up to 84 weeks.] [Designated as safety issue: No]
  From the date of randomization to the date of second disease progression

Other Outcome Measures:

- Quality of Life Questionnaire (QLQ) [Time Frame: Prior to initial dose on day 1 and after the last dose of each treatment] [Designated as safety issue: No]
  QLQ-C30 ver 3.0 QLQ specific for gastrointestinal neuroendocrine tumors (GINET21)

- Overall survival (OS) [Time Frame: Up to 84 weeks] [Designated as safety issue: No]

Estimated Enrollment: 180
Study Start Date: October 2014
Estimated Study Completion Date: December 2018
Estimated Primary Completion Date: September 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Sequence A, drug: everolimus first Everolimus (10mg/daily, oral) followed by STZ-5FU (injection/infusion; Moertel or Uppsala regime).	Drug: Drug: Everolimus 10mg/daily, oral. Number of Cycles: until progression or unacceptable toxicity develops. Other Name: Afinitor Drug: STZ-5FU 0,5g/m2 STZ on days 1-5 and 400mg/m2 5-FU on days 1-5 every 6 weeks (Moertel) or 0,5g/m2 STZ on days 1-5 and 400mg/m2 5-FU on days 1-5, and then 1 day with 1g/m2 and 1 day 400mg/m2 5-FU every 3 weeks (Uppsala). Number of Cycles: until progression or unacceptable toxicity develops. Other Name: STZ based Chemotherapy
Experimental: Sequence B, drug: STZ - 5FU first STZ-5FU (injection/infusion; Moertel or Uppsala regime) followed by Everolimus (10 mg/ daily, oral)	Drug: Drug: Everolimus 10mg/daily, oral. Number of Cycles: until progression or unacceptable toxicity develops. Other Name: Afinitor Drug: STZ-5FU 0,5g/m2 STZ on days 1-5 and 400mg/m2 5-FU on days 1-5 every 6 weeks (Moertel) or 0,5g/m2 STZ on days 1-5 and 400mg/m2 5-FU on days 1-5, and then 1 day with 1g/m2 and 1 day 400mg/m2 5-FU every 3 weeks (Uppsala). Number of Cycles: until progression or unacceptable toxicity develops. Other Name: STZ based Chemotherapy

Detailed Description:
STZ based chemotherapy, STZ-5FU, is the actual standard of care for advanced pancreatic Neuroendocrine tumours (pNETS) in the European Union. Everolimus has been recently approved for its use in advanced pNETs by the Food and Drug Administration (FDA) and in Europe by the European Medical Agency (EMA).

A randomized study is needed to have a clear knowledge about the best sequence for its administration; this is, before or after palliative chemotherapy.

There may or may not be any benefits from giving first each other treatment of the study. The information obtained from this study will help the physician improve the treatment and management of patients with advanced pNET.

Eligibility

Ages Eligible for Study: 18 Years to 94 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

- Histologically proven diagnosis of unresectable or metastatic, advanced pancreatic NET.
- Documented confirmation of pancreatic NET G1 or G2 as per European Neuroendocrine Society (ENETS) classification system.
- Patients from whom a paraffin-embedded primary tumour or metastasis block is available and sent by Courier.
- Before study inclusion, patients must show progressive disease documented by radiology 12 months prior to study inclusion. Naive patients can be also included if the patient needs active treatment with either chemotherapy or everolimus.
- Presence of measurable disease as per Response Evaluation Criteria in Solid Tumors (RECIST) criteria 1.0, documented by a Triphasic Computed Tomography (CT) scan or multiphase MRI radiological assessment.
- Previous treatment with somatostatin (SS) analogues is allowed. Only those patients with active functioning syndrome at entry can continue with SS analogues during the study.
- Adequate bone marrow and renal functions, and serum fasting cholesterol
- Women with child-bearing potential must have a negative serum pregnancy test.
- Written Informed Consent obtained according to local regulations

Exclusion Criteria:

- Previous treatment with chemotherapy and/or mTOR inhibitors or tyrosine kinase inhibitors.
- Immune therapy or radiation therapy within 4 weeks prior to the patient entering the study.
- Hepatic artery embolization within the last 6 months (1 month if there are other sites of measurable disease), or cryoablation/radiofrequency ablation of hepatic metastasis within 2 months of enrolment.
- Previous treatment with Peptide-Receptor Radionuclide Therapy (PRRT) within the last 6 months and/or without progression following PRRT.
- Uncontrolled diabetes mellitus.
- Any severe and/or uncontrolled medical conditions.
- Treatment with potent inhibitors or inducers of Cytochrome P450 3A4 (CYP3A) isoenzyme within 5 days immediately before the start of treatment.
- Patients on chronic treatment with corticosteroids or any other immunosuppressive agent.
- Patients known to be HIV seropositive.

- Known intolerance or hypersensitivity to everolimus or its excipients or other rapamycin analogues. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.
- Known intolerance or hypersensitivity to 5FU or STZ or its excipients.
- Pregnant, lactating women or fertile adults not using effective birth control methods.
- For administrative matters (insurance) patients ≥ 95 are not allowed.

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: NCT02246127

Contacts

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Locations

Denmark

Morten Ladekarl Aarhus, Denmark, 8000	**Recruiting**
Ulrich Peter Knigge Copenhagen, Denmark, 2100	**Recruiting**
Lene Vestermark Odense, Denmark, 5000	**Recruiting**

France

Jean-Philippe Metges Brest, Brest Cedex, France, 29609	**Recruiting**
Philippe Ruszniewski Clichy, Clichy Cedex, France, 92118	**Recruiting**
Bernard Goichot Strasbourg, Strasbourg Cedex, France, 67098	**Recruiting**
Denis Smith Bordeaux, France, 33075	**Recruiting**
Thomas Walter Lyon, France, 69437	**Recruiting**

Germany

Dieter Hörsch Bad Berka, Germany, 99437	**Recruiting**
Joerg Schrader Hamburg, Germany, 20246	**Recruiting**
Birgit Cremer Köln, Germany, 50937	**Recruiting**
Peter Malfertheiner Magdeburg, Germany, 39120	**Recruiting**
Anja Rinke Marburg, Germany, 35033	**Recruiting**
Bruno Neu München, Germany, 81675	**Recruiting**
Christoph Josef Auernhammer München, Germany, 81377	**Recruiting**

Italy

Carlo Carnaghi Rozzano, Milan, Italy	**Recruiting**
Salvatore Tafuto Naples, Italy, 80131	**Recruiting**

Netherlands

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Spain

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Jaume Capdevila Barcelona, Spain, 08035	**Recruiting**
Marta Martin Barcelona, Spain, 08025	**Recruiting**
Maria Isabel Sevilla Málaga, Spain, 29010	**Recruiting**
Marta Benavent Sevilla, Spain, 41013	**Recruiting**

Sweden

Barbro Eriksson Upsala, Sweden, 75185	**Recruiting**

Sponsors and Collaborators

Grupo Espanol de Tumores Neuroendocrinos
European Neuroendocrine Tumor Society
Kantar Health
Novartis Pharmaceuticals

Investigators

Principal Investigator: Salazar Ramon, MD, PhD Instituto Catalán de Oncologia, ICO-Hospitalet

More Information

No publications provided

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Keywords provided by Grupo Espanol de Tumores Neuroendocrinos:
advanced pNET
everolimus
STZ-5FU
treatment sequence

Additional relevant MeSH terms:

Adenoma, Islet Cell	Neoplasms, Glandular and Epithelial
Apudoma	Neoplasms, Nerve Tissue
Carcinoid Tumor	Neuroectodermal Tumors
Neuroendocrine Tumors	Pancreatic Diseases
Adenocarcinoma	Pancreatic Neoplasms
Adenoma	Everolimus
Carcinoma	Sirolimus
Digestive System Diseases	Anti-Bacterial Agents
Digestive System Neoplasms	Anti-Infective Agents
Endocrine Gland Neoplasms	Antibiotics, Antineoplastic
Endocrine System Diseases	Antifungal Agents
Neoplasms	Antineoplastic Agents
Neoplasms by Histologic Type	Immunologic Factors
Neoplasms by Site	Immunosuppressive Agents
Neoplasms, Germ Cell and Embryonal	Pharmacologic Actions

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