Purpose

The purpose of the study is to evaluate the efficacy and tolerability of the combination of Lanreotide Autogel 120 mg and Temozolomide in patients with progressive gastro-entero-pancreatic neuroendocrine tumours (GEP-NET) graded as G1 or G2 (G1/G2). All progressive tumours classified according to Response Evaluation Criteria in Solid Tumours (RECIST, 1.1).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
</table>
| Gastroenteropancreatic Neuroendocrine Tumors | Drug: Lanreotide Autogel 120 mg  
Drug: Temozolomide (TMZ)          | Phase 2 |

Study Type: Interventional  
Study Design: Endpoint Classification: Efficacy Study  
Intervention Model: Single Group Assignment  
Masking: Open Label  
Primary Purpose: Treatment

Official Title: Phase II, Multicentre, Open Label Study to Evaluate the Efficacy of the Combination of Lanreotide Autogel 120 mg and Temozolomide in Patients With Progressive Gastro-entero-pancreatic Neuroendocrine Tumours (GEP-NET) G1/G2 - A Pilot-Study

Resource links provided by NLM:

MedlinePlus related topics: Cancer

Drug Information available for: Temozolomide Lanreotide Lanreotide acetate

Genetic and Rare Diseases Information Center resources: Gastro-enteropancreatic Neuroendocrine Tumor Neuroepithelioma Pancreatic Cancer Stomach Carcinoma

U.S. FDA Resources

Further study details as provided by Ipsen:

Primary Outcome Measures:

- Disease control rate after 6 months [ Time Frame: 6 months ] [ Designated as safety issue: No ]
  
  Disease control rate is the total proportion of patients in each category of response i.e. Complete response + partial response + stable disease as measured by the central radiologist using (RECIST, 1.1).
Secondary Outcome Measures:

- **Disease control rate after 12 months** [Time Frame: 12 months] [Designated as safety issue: No]
  
  Disease control rate is the total proportion of patients in each category of response i.e. Complete response + partial response + stable disease as measured by the central radiologist using (RECIST, 1.1). [6 months combination treatment followed by either 6 months Lanreotide ATG 120 mg maintenance or 6 months wait and see].

- **Time to disease progression or death** [Time Frame: up to 12 months] [Designated as safety issue: No]

- **Percentage of patients with normalized and stabilized Chromogranin A (CgA) levels after 6 months** [Time Frame: 6 months] [Designated as safety issue: No]
  
  Defined as less than 50% increase of CgA level compared to baseline

- **Percentage of patients with normalized and stabilized CgA-levels after 12 months** [Time Frame: 12 months] [Designated as safety issue: No]
  
  Defined as less than 50% increase of CgA level compared to baseline

- **Time to partial response within 12 months** [Time Frame: 12 months] [Designated as safety issue: No]

- **Time to complete response within 12 months** [Time Frame: 12 months] [Designated as safety issue: No]

- **Duration of partial response within 12 months** [Time Frame: 12 months] [Designated as safety issue: No]

- **Duration of complete response within 12 months** [Time Frame: 12 months] [Designated as safety issue: No]

- **Percentage change (greater than or equal to 50%) from baseline in CgA reduction at 12 months** [Time Frame: Baseline, 12 months] [Designated as safety issue: No]

- **Change from baseline in frequency of symptomatic episodes of diarrhoea after 6 months** [Time Frame: Baseline, 6 months] [Designated as safety issue: No]
  
  Frequency of the symptomatic episodes assessed by the mean of the last 3 days before the patient visit

- **Change from baseline in frequency of symptomatic episodes of flushing after 6 months** [Time Frame: Baseline, 6 months] [Designated as safety issue: No]
  
  Frequency of the symptomatic episodes assessed by the mean of the last 3 days before the patient visit

- **Change from baseline in frequency of symptomatic episodes of diarrhoea after 12 months** [Time Frame: Baseline, 12 months] [Designated as safety issue: No]
  
  Frequency of the symptomatic episodes assessed by the mean of the last 3 days before the patient visit

- **Change from baseline in frequency of symptomatic episodes of flushing after 12 months** [Time Frame: Baseline, 12 months] [Designated as safety issue: No]
  
  Frequency of the symptomatic episodes assessed by the mean of the last 3 days before the patient visit

- **Change from baseline in Quality of Life (QoL)** [Time Frame: Baseline, 6 months] [Designated as safety issue: No]

  QoL assessed using the European Organization for the Research and Treatment of Cancer Quality of Life Core 30 (EORTC QLQ-C30) and Quality of Life Gastrointestinal Neuroendocrine Tumour 21 (QLQ-GI.NET21) Questionnaires.

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**Estimated Enrollment:** 40

**Study Start Date:** October 2014

**Estimated Study Completion Date:** October 2018

**Estimated Primary Completion Date:** October 2018 (Final data collection date for primary outcome measure)

**Arms**

<table>
<thead>
<tr>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experimental: Lanreotide Autogel 120mg &amp; Temozolomide</strong></td>
</tr>
<tr>
<td>Combination phase for first 6 months: Lanreotide Autogel 120 mg and Temozolomide.</td>
</tr>
<tr>
<td>Followed by either 6 months Lanreotide Autogel 120 mg maintenance or 6 months of no treatment.</td>
</tr>
<tr>
<td><strong>Drug: Lanreotide Autogel 120 mg</strong></td>
</tr>
<tr>
<td>Lanreotide Autogel 120 mg subcutaneous (s.c) - injection, every 28 days (+/-2 days).</td>
</tr>
<tr>
<td><strong>Drug: Temozolomide (TMZ)</strong></td>
</tr>
<tr>
<td>Temozolomide capsule (variable dose). 150 mg/m² per day for 5 days in the first month. 200 mg/m² per day for 5 days in months 2, 3, 4, 5 and 6.</td>
</tr>
</tbody>
</table>
Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Provision of written informed consent prior to any study related procedures
- Inoperable, Gastro-Entero-Pancreatic-Neuroendocrine Tumour G1 or G2 (Proliferation Index, Ki67-Index: 0 to ≤20%) confirmed by pathological/histological assessment
- Progressive disease within 12 months before inclusion (RECIST 1.1: increase of >20% tumour load; by Computer Tomography (CT) or Magnetic Resonance Imaging (MRI))
- Measurable disease according to RECIST 1.1.
- Metastatic disease confirmed by CT/MRI.
- Functioning or non-functioning NET (G1, G2).
- Positive Octreo-Scan (≥ Grade 2 Krenning scale) or positive DOTA (1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid)-TATE (Tyr3-Thre8-Octreotide or DOTA-Tyr3-octreotate)/TOC (Tyr3-octreotide) -PET (Positron-Emission-Tomography) -CT within 12 months prior to screening

Exclusion Criteria:
- Has the diagnosis of Insulinoma
- Has a diagnosis of a multiple endocrine neoplasia (MEN)

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: NCT02231762

Contacts

Contact: Ipsen Recruitment Enquiries  clinical.trials@ipsen.com

Locations

Austria
Vienna General Hospital
Vienna, Austria, 1090
Not yet recruiting

Germany
Zentralklinik Bad Berka
Bad Berka, Germany, 99437
Not yet recruiting
Charité University Hospital
Berlin, Germany, 13353
Not yet recruiting
University Hospital Essen
Essen, Germany, 45122
Not yet recruiting
ENDOC Hamburg
Hamburg, Germany, 20357
Not yet recruiting
Oncological Center Leer
Leer, Germany, 26789
Not yet recruiting
University Hospital Mainz
Mainz, Germany, 55131
Not yet recruiting
University Hospital Mannheim
Mannheim, Germany, 68167
Not yet recruiting
Sponsors and Collaborators
Ipsen

Investigators
Study Director: Philipp Hoffmanns, MD, PhD, MBA Ipsen

More Information
No publications provided

Responsible Party: Ipsen
ClinicalTrials.gov Identifier: NCT02231762
Other Study ID Numbers: A-94-52030-268, 2013-001697-17
Study First Received: September 2, 2014
Last Updated: November 3, 2014
Health Authority: Germany: Federal Institute for Drugs and Medical Devices
Austria: Agency for Health and Food Safety

Additional relevant MeSH terms:
Intestinal Neoplasms
Neuroendocrine Tumors
Pancreatic Neoplasms
Stomach Neoplasms
Digestive System Diseases
Endocrine Gland Neoplasms
Endocrine System Diseases
Gastrointestinal Diseases
Gastrointestinal Neoplasms
Intestinal Diseases
Neoplasms
Neoplasms by Histologic Type
Neoplasms by Site
Neoplasms, Germ Cell and Embryonal

ClinicalTrials.gov processed this record on November 16, 2014