Somatostatin receptor expression and occupancy during lanreotide therapy

Published: 28-02-2014
Last updated: 15-02-2024

The goal of this study is to visualize and quantify the somatostatin receptor expression and occupancy directly before and after the injection of long-acting lanreotide in NET patients by imaging with [68Ga]-DOTATATE PET.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON53159

Source
ToetsingOnline

Brief title
Somatostatin receptor occupancy

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
hormone producing tumor, Neuroendocrine tumor

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ipsen Pharmaceuticals

Intervention

Keyword: [68Ga]-Dotatate, Lanreotide, Neuroendocrine tumor

Outcome measures

Primary outcome

To visualize and quantify the difference in somatostatin receptor occupancy directly before and after lanreotide injection.

Secondary outcome

a. To assess a correlation between tumor [68Ga]-DOTATATE uptake and size in relation to lanreotide binding.

b. To assess differences in [Ga68]-DOTATATE uptake and behavior (reaction to lanreotide) between different metastasis in 1 patient.

c. To assess the differences in uptake in normal tissue (thyroid, spleen, liver etc.) before and after lanreotide.

d. To assess the correlation between clinical symptoms, receptor occupancy, and tumor markers.

Study description

Background summary

Patients with NETs who are treated with long-acting lanreotide can experience an increase in clinical symptoms and/or tumor markers while on treatment. The reason(s) behind somatostatin analogue tachyphylaxis and resistance are not yet fully understood, but different methods have been proposed, such as receptor down-regulation or desensitization, or an increased expression of other (non-targeted) receptor subtypes, or mutation of the receptor. Knowledge about receptor occupancy will also become more important when lanreotide (and other somatostatin analogues) is not only used for the treatment of carcinoid symptoms but also as anti-proliferative treatment.

Study objective

The goal of this study is to visualize and quantify the somatostatin receptor expression and occupancy directly before and after the injection of long-acting lanreotide in NET patients by imaging with [68Ga]-DOTATATE PET.

Study design

Patients with a NET that are treated with lanreotide and are scheduled for a [68Ga]-DOTATATE PET/CT scan the day before lanreotide treatment, will be approached for a second [68Ga]-DOTATATE PET/CT scan the day after lanreotide treatment. Clinical decision-making will be based on the first scan, the second scan is additional and for research purposes only.

A schedule for one patient is as follows:
Day 1: [68Ga]-DOTATATE PET/CT scan as planned
Day 2: Lanreotide injection as planned
Day 3: Additional [68Ga]-DOTATATE PET/CT scan

All sequential scans will be compared by a nuclear medicine physician (blinded) for differences in biodistribution. Furthermore, all scans will be quantified by using a standard software package and expressed in a standardized uptake value (SUV) and tumor to background ratio. The uptake (SUV) will be measured in all lesions visualized on either one of the PET-scans and compared with each other.

Study burden and risks

Patients are asked to undergo 1 extra PET scan for this study. The burden of this is one extra hospital visit of approximately 1.5 hours. There are no known side-effects of [Ga68]-DOTATATE PET.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- >=18 years old
- Histologically confirmed low and intermediate grade NET
- Metastatic or unresectable disease
- Measurable disease on [68Ga]-DOTATATE PET-scan
- WHO performance status less than 2
- Life expectancy more than 3 months
- Long-acting lanreotide treatment for at least 4 months

Exclusion criteria

- Pregnant or breast-feeding
- Claustrophobic

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-01-2015

Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL45948.031.13