Exendin PET/CT for imaging of paragangliomas

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The primary objective is to examine the feasibility of 68Ga-exendin-4 PET/CT for localizing and characterizing PGL.

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

Summary

ID

NL-OMON50901

Source
ToetsingOnline

Brief title
ENTRAP

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
Paraganglioma

Research involving
Human

Sponsors and support

Primary sponsor: Nucleaire geneeskunde en radiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exendin PET, Paraganglioma

Outcome measures

Primary outcome

Detection rate of PGLs using 68Ga-exendin-4 PET/CT

Secondary outcome

• Optimal timepoint for imaging PGLs using 68Ga-exendin-4 PET/CT.

• Comparison of quantitative imaging parameters (SUV, tumor-to-background ratio, contract-to-noise ratio) between 68Ga-exendin-4 PET and SSTR PET.

• Correlation between GLP-1R expression and tracer uptake in the PGLs.

• Correlation quantitative imaging results and IHC data to the genetic origin of the PGLs.

Study description

Background summary

Because of the variability in genetic origin amongst paragangliomas (PGLs), functional imaging is not unequivocal. Existing methods show good but variable results, warranting the search for additional molecular imaging targets. We aim to evaluate the glucagon-like peptide 1 receptor (GLP-1R) as a novel target for molecular imaging of PGLs. For this we will use the tracer 68Ga-NODAGA-exendin 4 for positron emission tomography/ computed tomography (PET/CT) imaging.

Study objective

The primary objective is to examine the feasibility of 68Ga-exendin-4 PET/CT for localizing and characterizing PGL.

Study design

In this prospective pilot imaging study we will perform 68Ga-exendin-4 PET/CT in 10 patients with confirmed PGL who have undergone CT and somatostatin receptor (SSTR) PET/CT and are scheduled for surgery. We will administer 100 ± 5 MBq 68Ga-NODAGA-exendin-4 to 10 patients in total. In the first 3 patients we will perform PET/CT imaging 1, 2 and 4 hours after injection to determine the

optimal imaging timepoint, which will be applied in the remaining patients.
The images will be reconstructed and evaluated by a nuclear medicine physician who is blinded to the results of the CT and SSTR PET/CT to assess tumor detection. Additionally, quantitative analysis of 68Ga-exendin-4 and SSTR PET images will be performed. After the patients have undergone surgery, immunohistochemical analysis of surgical specimens will be performed to assess GLP-1R expression and correlate this with in vivo tracer uptake. Imaging and immunohistochemistry (IHC) results will be correlated to the genetic origin of the PGLs.

Study burden and risks

Potential adverse events that could occur based on the pharmacological effects of 68Ga-NODAGA-exendin-4 and the observations in clinical trials with exenatide so far namely include hypoglycaemia following injection and nausea with vomiting. These effects are expected to be less pronounced than in previous studies because the injected peptide amount will be more than 10 times lower. Also, PGL patients are less prone to develop hypoglycaemia because of the overproduction of catecholamines, which promotes hyperglycaemia. As hypoglycaemia requires immediate stabilization of the glucose homeostasis, blood glucose levels will be followed for 2 hours after injection. Upon lowering of blood glucose levels, these will be stabilized using intravenous glucose infusion if needed.
Next to this, potential adverse events could occur because of the cardiovascular effects (hypotensiona and tachycardia) of 68Ga-NODAGA-exendin-4. These effects are expected to be minimal because of the low peptide dose of the tracer and the short-acting nature of exendin-4. To monitor these effects, heart rate and blood pressure of all patients will be monitored until 2 hours after injection.
The total expected radiation dose (68Ga en CT) expected from the PET/CT scan is very low; about 5.1 mSv .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Proven PGL with a single tumor detected using standard diagnostic imaging
• No evidence of metastatic disease
• SSTR PET performed
• Scheduled for surgery
• Able to sign informed consent

Exclusion criteria

• Breast feeding
• Pregnancy or the wish to become pregnant within 1 month
• Calculated creatinine clearance below 40ml/min
• Evidence of other malignancy than PGL in conventional imaging (suspicious liver, bone and lung lesions)
• Age < 18 years
• Not able to sign informed consent

Study design

Design

Study phase: 2

Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	68Ga-NODAGA-exendin-4
Generic name:	68Ga-exendin-4

Ethics review

Approved WMO Date:	26-07-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2021-000194-93-NL
CCMO	NL76538.091.21