[18F]mFBG PET-CT imaging of pheochromocytoma

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This study has been transitioned to CTIS with ID 2024-513622-35-00 check the CTIS register for the current data. The primary objective of this study is to assess the number of detected pheochromocytoma lesions, proved by histology, with [18F]mFBG...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON50866

Source
ToetsingOnline

Brief title
mFBG PCC

Condition

- Adrenal gland disorders
- Endocrine neoplasms benign

Synonym
Pheochromocytoma - endocrine adrenal tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: imaging, mFBG PET-CT, pheochromocytoma

Outcome measures

Primary outcome

The number of detected pheochromocytoma lesions, proved by histology, with pathological [18F]mFBG uptake, defined as focal uptake above surrounding normal tissue, compared to number of lesions detected on protocollary conventional CT imaging prior to surgery.

Secondary outcome

1) Optimal time point of [18F]mFBG PET-CT imaging via comparison of SUV values at 1 and 2 hours on PET-CT imaging.

2) Correlation of [18F]mFBG PET findings with pathology and immunohistochemistry analysis of norepinephrine transporter.

3) Estimation of radiation dose of [18F]mFBG in normal tissues using dynamic PATLAK imaging

4) Safety analysis of [18F]mFBG administration on clinical symptoms will be evaluated by Adverse Events outcomes

Study description

Background summary

Pheochromocytomas are rare neuroendocrine tumors with a high variability in clinical presentation. In current diagnostics, a CT is recommended as the first screening modality. Next step in diagnostics was earlier a [123I]mIBG scan, but this technique has drawbacks, namely a relatively low resolution due to gamma camera imaging, long acquisition times, necessary protection for the thyroid gland and a two-day scan protocol. [18F]mFBG is a new radionuclide tracer

(similar to [123I]mIBG), but with the advantages of higher resolution, no necessary thyroid protection and a one-day scanning protocol. We want to compare this new [18F] mFBG PET-CT tracer with CT. In case of good accuracy in detecting pheochromocytomas, [18F]mFBG could also be used for paragangliomas. This is important because paragangliomas are often missed during screening.

Study objective

This study has been transitioned to CTIS with ID 2024-513622-35-00 check the CTIS register for the current data.

The primary objective of this study is to assess the number of detected pheochromocytoma lesions, proved by histology, with [18F]mFBG PET-CT compared to the conventional CT.

Study design

Phase 2 imaging study

Study burden and risks

Patients will undergo an additional [18F]mFBG PET-CT. The extra expected radiation dose is 9.6mSv, which is comparable to the radiation exposure one receives on 4-yearly basis in nature. The time burden for this study is maximal 3 hours, which can be seen as a low burden. The information obtained with [18F]mFBG PET-CT will be discussed in the weekly neuroendocrine multidisciplinary tumour board and used in clinical decision making. [18F]mFBG PET-CT may provide helpful information and may detect additional metastases or paraganglioma locations that might have clinical consequences. Also PET imaging might detect disease more accurately, leading to better tailored surgical and/or radiation therapy treatments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The patient has provided written informed consent authorization before participating in the study.
- The patient is >=18 years of age at the time of consent.
- The patient has a diagnosis of pheochromocytoma with a known anatomical location or laboratory findings suspicious for pheochromocytoma defined as elevated serum/plasma metanefrines.
- The patient should have surgery planned.
- The patient should have had a CT scan not older than 8 weeks at time of the [18F]mFBG PET-CT..
- The patient has an ECOG status of Grade 0 - 2.

Exclusion criteria

- Patient is mentally or legally incapacitated.
- Patient is pregnant or lactating.
- Patient has active serious infections not controlled by antibiotics.
- Patient is unable or unwilling to undergo PET-CT scanning or surgery.
- Patient did receive interfering treatment between conventional CT scanning and [18F]mFBG PET-CT.

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):	30-05-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	1-(3-[18F]fluorobenzyl)guanidine
Generic name:	mFBG

Ethics review

Approved WMO Date:	23-07-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-09-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	13-02-2024

Application type:	Amendment
Review commission:	METC NedMec

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
EU-CTR	CTIS2024-513622-35-00
EudraCT	EUCTR2020-005157-24-NL
CCMO	NL75688.041.21