

Prospective, primarily direct comparison of 11C-methionine PET versus 11C-choline PET, and secondary 4D-CT, to explore what PET tracer to use and in which order to use the functional versus the anatomical imaging technique in the setting of primary hyperparathyroidism

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Ethical review	Approved WMO
Status	Completed
Health condition type	Parathyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON45780

Source

ToetsingOnline

Brief title

PARROT

Condition

- Parathyroid gland disorders

Synonym

primary hyperparathyroidism; overactive parathyroid gland

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 11C-choline PET, 11C-methionine PET, 4D-CT, primary hyperparathyroidism

Outcome measures**Primary outcome**

Primary outcome is the performance (sensitivity) of 11C-MET PET/CT and 11C-choline PET/CT to detect parathyroid adenoma(s) in patients with primary hyperparathyroidism

Secondary outcome

Secondary outcome is the positive predictive value (PPV) of 11C-MET PET/CT and 11C-choline PET/CT and the performance (sensitivity and PPV) of 4D-CT to detect PTA in this setting. Sensitivities of all imaging techniques will be compared based on the confidence interval.

Study description**Background summary**

Surgery is the recommended and only curative treatment in patients with pHPT, preferably by means of a minimally invasive parathyroidectomy (MIP). During MIP, surgeons remove the parathyroid adenoma (PTA) via a unilateral approach with a minimal invasive incision (1-2 cm). In 80-90% only one PTA is present, making focused MIP usually successful.

In order to perform a MIP, accurate preoperative imaging is essential. Worldwide, the current primary preoperative localization-imaging-standard consists of cervical ultrasonography combined with MIBI-SPECT. When these techniques are combined a sensitivity of 80-95% can be achieved. However, this still means that surgeons will have to explore bilaterally in 5-20% of the cases. 11C-methionine positron emission tomography/CT (11C-MET PET/CT) and 11C-choline PET/CT are nuclear imaging techniques that can be used as a next step for imaging after prior negative localization. Also, a relatively new preoperative imaging modality was introduced in 2006 namely four-dimensional computerized tomography (4D-CT). If these scans do detect a parathyroid adenoma, surgeons can perform a minimal invasive parathyroidectomy. This minimal invasive approach has less complications, such as infections, bleedings or nerve damage.

Within the nuclear medicine department, it remains unclear which PET scan (using 11C-methionine or 11C-choline as a tracer) should be performed after a negative MIBI-SPECT/CT and/or cUS. In this area more research is warranted, to explore what and in which order to use the imaging techniques in the setting of pHPT, in order to perform a focused MIP.

Study objective

Prospective, primarily direct comparison of 11C-methionine PET versus 11C-choline PET, and secondary 4D-CT, to explore what PET tracer to use and in which order to use the functional versus the anatomical imaging technique in the setting of primary hyperparathyroidism

Study design

This is a single-center, prospective, blinded cohort study designed to compare primarily the sensitivity and PPV of 11C-MET PET/CT with 11C-choline PET/CT and secondary 4D-CT in operable patients with biochemically proven pHPT and prior negative, inconclusive or discordant parathyroid imaging with an indication for surgery.

Patients will follow the standard clinical work-up to undergo parathyroidectomy, including lab parameters, 11C-MET PET/CT, and if necessary 4D-CT. Patients participating in this study, after having given informed consent, will undergo additional imaging to the standard clinical care; namely 11C-choline PET/CT and if not already performed 4D-CT.

Intervention

Not applicable

Study burden and risks

Imaging is very important in patients with primary hyperparathyroidism (pHPT) in order to detect enlarged parathyroid glands with the aim of performing a minimal invasive parathyroidectomy (MIP). In this study we want to evaluate and compare 11C-methionine PET/CT, 11C-choline-PET/CT and 4D-CT to each other, in patients with pHPT and prior negative, inconclusive or discordant imaging, to explore what functional tracer is best and in which order to use the functional and anatomical imaging. Results of this study will provide valuable information about the performance of the imaging techniques in patients with pHPT and in which order to use them. For some patients with pHPT and prior negative/inconclusive/discordant imaging, the 11C-methionine PET/CT (and 4D-CT) is negative. Normally these patients would then be scheduled for a bilateral neck exploration. Because of this study, it is foreseen that the 11C-choline-PET/CT (or 4D-CT) will identify the PTA and these patients can then still be scheduled for a MIP. So, the benefits may be a less invasive and shorter procedure, resulting in less time under anesthesia and less time spent in the operation room. However, in some of the patients it is also possible that the extra imaging techniques are unnecessary (because 11C-MET PET/CT already identified the PTA, or all the techniques come up negative). For these patients the benefits of this study do not directly apply. Nevertheless, their participation helps to get more insight into the most sensitive PET tracer for the identification of PTA and the order in which the 11C-methionine PET/CT, 11C-choline-PET/CT and 4D-CT should be applied.

Since patients undergo an extra PET/CT and in some cases a 4D-CT scan, it will cause additional radiation burden to the patient. 11C-choline-PET/CT implements a radiation burden of about 2.3 mSv. A 4D-CT results in a radiation burden of 2.5 mSv. This totals to an extra 2.3 mSv (11C-choline PET only) or 4.8 mSv (11C-choline PET + 4D-CT) for patients participating in this study. Together the risk category of this study falls in category IIb. Also, patients may be allergic for the iodinated contrast fluid used in 4D-CT, resulting in a worst case scenario in shock. While serious allergic to contrast fluids are (very) rare, radiology departments are well-equipped to deal with them.

Whenever possible, for patient convenience, the 11C-choline PET/CT is preferably planned on the same day as the 4D-CT. It is not possible to plan the 11C-choline PET/CT on the same day as the 11C-methionine PET/CT. If the 11C-choline PET/CT cannot be planned on the same day as the 4D-CT, for this study, patients will pay maximum two extra visits to the hospital for the 11C-choline-PET/CT and in some cases the 4D-CT. Thereafter, patients will receive the parathyroidectomy as planned.

In conclusion, the risk associated with the extra 11C-choline-PET/CT and 4D-CT seems minor and although some of the patients may not directly benefit from this study, results of this study will be valuable for our understanding of the identification of PTA and the order in which the imaging techniques have to be used to identify them.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Patients ≥ 18 years
2. Patients have biochemically confirmed primary hyperparathyroidism
 - a. Patients with recurrent primary hyperparathyroidism (calcium levels prior normalized for at least one year) will be eligible for inclusion
3. Patients with prior negative, inconclusive or discordant localizing imaging on MIBI(-SPECT/(CT)) and/or cUS as concluded at the MDO.
4. Patients have an indication for parathyroidectomy
5. Patients are eligible for surgery
6. Patients are able to give informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Patients with a germline mutation predisposing for multiple gland disease
2. Patients with an alternative diagnosis (e.g. parathyroid carcinoma) known before surgery
3. Patients with a previous negative neck exploration for pHPT
4. Patients with persistent pHPT
5. Patients with renal dysfunction, eGFR < 30 ml/min*1.73 m²
6. Patients with known allergy for iodinated contrast
7. Pregnant patients

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 29-03-2019

Enrollment: 30

Type: Actual

Medical products/devices used

Product type: Medicine

Brand name: 11C-choline

Generic name: 11C-choline

Ethics review

Approved WMO

Date: 09-11-2018

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2018-001369-18-NL
CCMO	NL65886.042.18

Study results

Date completed: 06-06-2023

Results posted: 16-04-2024

Actual enrolment: 32

First publication

01-01-1900