Additional imaging techniques for localizing parathyroid adenomas in patients with primary hyperparathyroidism

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24844

Source
NTR

Brief title
PARROT

Health condition

Primary hyperparathyroidism

Keywords:
pHPT
Imaging
11C-methionine PET/CT
11C-choline PET/CT
4D-CT

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

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) (PTA) 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 of 4D-CT (sensitivity and PPV) to detect parathyroid adenomas in patients with primary hyperparathyroidism.

Study description

Background summary

Rationale: In the setting of primary hyperparathyroidism (pHPT) caused by a parathyroid adenoma (PTA), it remains unclear which PET tracer has the highest sensitivity after a negative MIBI-SPECT/CT and/or neck ultrasound (cUS), 11C-methionine PET (11C-MET PET) or 11C-choline-PET. In this area more research is warranted, to explore what and in which order to use the imaging techniques in the setting of pHPT, to be able to perform a focused minimal invasive parathyroidectomy (MIP).

Objective: To perform a prospective study aiming to primarily directly compare the 11C-MET PET with 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: Single-center, prospective, blinded cohort study.

Study population: Patients (¡Ý18 year) with biochemically confirmed pHPT and prior negative, inconclusive or discordant localizing imaging who have an indication for parathyroidectomy and are eligible for surgery.

Main study parameters/endpoints: Primary outcome is the performance (sensitivity), of 11C-MET PET/CT and 11C-choline PET/CT to detect parathyroid adenoma(s) (PTA) in patients with pHPT. The gold standard are final results from surgery, pathology and laboratory values combined. Secondary outcome is the positive predictive value (PPV) of 11C-MET PET/CT and 11C-choline PET/CT and the performance of 4D-CT (sensitivity and PPV) to detect PTA in this setting. Sensitivities will be compared based on the confidence interval.

Study design

Sensitivity: 2 years

Positive predictive value: 2 years

Intervention

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.

Patients will undergo 11C-methionine PET/CT, as is standard clinical care.
The outcome of these imaging techniques will be compared with each other.

Contacts

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Eligibility criteria

Inclusion criteria

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

1. Patients ¡Ý 18 years

2. Patients have biochemically confirmed primary hyperparathyroidism (pHPT)

a. Patients with recurrent pHPT (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 primary hyperparathyroidism (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
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2018
Enrollment:	30
Type:	Unknown

Ethics review

Positive opinion

Date:	16-07-2018
Application type:	First submission

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
NTR-new	NL7224
NTR-old	NTR7423
Other	UMCG : 201800237

Study results