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

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24844

Bron
Nationaal Trial Register

Verkorte titel
PARROT

Aandoening

Primary hyperparathyroidism

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

Sensitivity: 2 years

Positive predictive value: 2 years

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Nucleaire Geneeskunde, HPC EB50

Milou E Noltes
Postbus 30.001

Groningen 9700 RB
The Netherlands
0610755161

Wetenschappelijk

Nucleaire Geneeskunde, HPC EB50

Milou E Noltes
Postbus 30.001

Groningen 9700 RB
The Netherlands
0610755161

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	30
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	16-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7224
NTR-old	NTR7423
Ander register	UMCG : 201800237

Resultaten