18F-Choline PET/CT for patients with primary hyperparathyroidism and negative SPECT/CT

Published: 06-01-2015
Last updated: 20-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Parathyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON40137

Source
ToetsingOnline

Brief title
PHPPET study

Condition

- Parathyroid gland disorders

Synonym
primary hyperparathyroidism ; overproduction Parathyroid Hormone

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: discordant findings, FCH PET/CT, primary hyperparathyroidism

Outcome measures

Primary outcome

The main outcome of the study is the performance of FCH PET/CT in localizing the pathological parathyroid gland(s) defined as PPV and sensitivity. This will be controlled by surgically removing the suspicious gland(s). If post-operative normalisation of the ICa level is found, surgery is considered successful. Therefore the endpoint of our study will be a normal blood hormone level of ICa one week after surgery.

Secondary outcome

NA

Study description

Background summary

Conventional pre-operative imaging in patients with primary hyperparathyroidism (PHP) includes neck ultrasound and Tc-99m-sestamibi SPECT/CT. When findings of conventional imaging are concordant patients undergo surgery with a minimally invasive approach (MIA). In 30 - 50 % of patients one of the imaging modalities is negative or the imaging is discordant. These patients cannot undergo MIA and the operation is either postponed or more extensive with neck exploration where all parathyroid glands have to be investigated.
18Fluor-choline (FCH) is a promising new PET tracer and there are reports that FCH has superior sensitivity for the detection of hyper functioning parathyroid glands. With the addition of FCH PET/CT we hope to optimize preoperative work-up allowing for MIA in patients with PHP.

Study objective

The primary objective of our study is to investigate the performance of FCH-PET as a second-line imaging modality for localizing hyper-functioning parathyroid

gland(s) in patients with biochemically proven PHP for whom surgery is indicated, thereby making them eligible for MIA. Only patients with negative SPECT/CT will be included.

Study design

Prospective diagnostic study investigating the accuracy of FCH PET/CT in localizing the hyper-functioning parathyroid gland(s).

Study burden and risks

Patients participating in the study with negative findings on conventional imaging will undergo additional FCH PET/CT imaging. The results of FCH PET/CT will be used for the pre-operative work-up of the patients thereby potentially allowing MIA.
The proposed study is considered safe and well tolerable. The risks of the extra FCH PET/CT are negligible and the benefits could possibly be MIA instead of more extensive surgical neck exploration.

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

- Patients who have signed informed consent;- Age >= 18 years;- Biochemically proven PHP;- Indication for surgery;- Negative SPECT/CT

Exclusion criteria

- Pregnancy ;- Patients with MEN syndrome

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	fluorocholine

Generic name:	FCH

Ethics review

Approved WMO Date:	06-01-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	04-02-2015
Application type:	First submission
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
EudraCT	EUCTR2014-004590-16-NL
CCMO	NL47508.041.14