Adrenal gland scanning using PET/CT with a specific tracer (11C-metomidate) in patients with hypertension due to overproduction of aldosterone.

No registrations found.

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

Summary

ID

NL-OMON28757

Source
NTR

Health condition

hypertension
primary aldosteronism
adrenal venous sampling

Sponsors and support

Primary sponsor: University Medical Center Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands
Source(s) of monetary or material Support: University Medical Center Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands

Intervention

Outcome measures

Primary outcome

Degree of concordance between results of 11C-metomidate PET/CT and those of AVS with respect to differentiation between BAH and APA.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Primary aldosteronism (PA) is a relatively common secondary cause of hypertension. PA is usually due to either bilateral adrenal hyperplasia (BAH) or an aldosterone producing adrenal adenoma (APA). Less frequently, PA is caused by primary unilateral adrenal hyperplasia (PAH). Clinically, PAH behaves like APA and the distinction between these two subtypes can only be made by pathologic examination of the removed adrenal gland, demonstrating either hyperplasia or adenoma, respectively. The recommended treatment for BAH is medical treatment with antihypertensive drugs (aldosterone antagonist), whereas APA and PAH can be cured in many cases by unilateral adrenalectomy. Thus, it is of clinical importance to differentiate correctly between BAH and APA/PAH. Current guidelines recommend adrenal venous sampling (AVS) as the gold standard for the differentiation between BAH and APA/PAH in every patient with PA who is a candidate for surgery. However, AVS is an invasive diagnostic test and is therefore not without risks. Moreover, AVS requires an experienced radiologist, and is time-consuming and expensive. Therefore, there is an urgent need for a non-invasive, faster and less expensive diagnostic test which can correctly distinguish between the two main subtypes of PA. PET/CT with 11C-metomidate has successfully been used as a functional imaging technique for several adrenal gland diseases. Until now, its value in the differential diagnosis in PA has not been well investigated. Our hypothesis is that 11C-metomidate PET/CT is selectively taken up by aldosterone producing adrenal cortical tissue, resulting in a symmetrical tracer uptake in case of BAH and in a unilateral tracer uptake in a patient with an APA or PAH.

Objective:

Main objective is to determine whether 11C-metomidate PET/CT can differentiate between BAH and APA/PAH.

Study design:

Comparative diagnostic study.

Study population:

Adult patients (=/> 18yrs) with PA after a successful AVS (n=10).

Intervention:

Patients will undergo a whole-body 11C-metomidate PET/CT scan.

Main study parameters/endpoints:

Main study parameter is the concordance between the results of AVS (=gold standard) and 11C-metomidate PET/CT.

Study objective

Our hypothesis is that 11C-metomidate is selectively taken up by aldosterone producing adrenal cortical tissue, resulting in a symmetrical tracer uptake in case of bilateral adrenal hyperplasia (BAH) and in a unilateral tracer uptake in a patient with an aldosterone producing adenoma (APA)or primary adrenal hyperplasia (PAH).

Study design

N/A

Intervention

Study subjects are pretreated with a 5-day course of 3 mg dexamethasone qd directly before scanning. The scanning procedure itself will take approximately 1.5 hours. Before arriving at the department, patients should have fasted for 4 hours. In the first part of the investigation, patients will receive an intravenously injection with 400 MBq 11C-metomidate. In the second part of the investigation, 20 minutes after tracer injection, patients will be placed for approximately 45 minutes in the PET/CT camera to acquire whole-body images (head to pelvis).

Contacts

Public
Department of Endocrinology
University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518
Scientific
Department of Endocrinology
University Medical Center Groningen
M.N. Kerstens
Groningen
The Netherlands
+31 (0)50 3616161/3518

Eligibility criteria

Inclusion criteria

1. Age =/> 18 years;

2. Primary aldosteronism (PA) with successfully performed adrenal venous sampling (AVS).

Exclusion criteria

1. Use of ketoconazole, metyrapone or cytostatic drugs during previous 6 months;

2. Pregnancy;

3. Severe contrast allergy;

4. Diabetes mellitus (type 1 or type 2);

5. Serious comorbidities precluding surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-01-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35185
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3629
NTR-old	NTR3817
CCMO	NL28866.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35185

Study results

Summary results
N/A