Diagnostic value of 11C-metomidate Positron Emission Tomography/Computerized Tomography (PET/CT) for the evaluation of primary aldosteronism: a pilot study

Published: 03-03-2010
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The objective of the study is to determine whether 11C-metomidate PET can differentiate between BAH and APA./PAH

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

Summary

ID

NL-OMON35185

Source
ToetsingOnline

Brief title
PET/CT in primary aldosteronism

Condition

- Adrenal gland disorders

Synonym
primary aldosteronism - Conn's syndrome - overactive adrenal gland with excessive secretion of aldosterone

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-metomidate PET/CT, functional imaging, primary aldosteronism

Outcome measures

Primary outcome

To establish with PET whether 11C-metomidate is selectively taken up by adrenal gland tissue with autonomic hypersecretion of aldosterone and that the distribution of tracer uptake by the adrenal glands (unilateral versus bilateral) is concordant with the results of AVS. Results are presented as percentages with 95%-confidence intervals.

Secondary outcome

Not applicable.

Study description

Background summary

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) or primary unilateral adrenal hyperplasia (PAH). The recommended treatment for BAH is antihypertensive medication, 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 safer, 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 is selectively taken up by aldosterone producing adrenal cortical tissue, resulting in a symmetrical tracer uptake during PET/CT in case of BAH and in a unilateral tracer uptake in a patient with an APA/PAH.

Study objective

The objective of the study is to determine whether 11C-metomidate PET can differentiate between BAH and APA./PAH

Study design

The present pilot study is a comparative diagnostic trial, in which a new method of functional imaging with 11C-metomidate PET/CT is compared with the current reference method of AVS in the evaluation of patients with PA. Both the patient and the nuclear medicine physician are blinded for the results of the previous AVS. Interpretation of the 11C-metomidate PET/CT is performed independently by two nuclear medicine physicians. After completion of 11C-metomidate PET/CT, each patient will receive standard treatment guided by the final diagnosis based on the AVS results (either medication or surgery).

Study burden and risks

Burden and risks:
- extra visit to the hospital (department of nuclear medicine)
- pretreatment with dexamethasone 1,5 mg b.i.d. during 5 days prior to 11C-metomidaat PET/CT
- time burden investigation (1.5 hour)
- 4 hours fasting prior to PET/CT. In case of concurrent diabetes mellitus, adjustment of hypoglycemic medication (oral agents and/or insulin) is indicated on the day of PET/CT
- risk of pain and/or hematoma due to venipuncture.
- radiation dose of a single 11C-metomidate PET/CT scan is equivalent to 3.2 mSv (11C-metomidate: 1.7 mSv, CT-scan: 1.5 mSv). According to the International Commission on Radiological Protection (ICRP 62), this radioation dose falls into category IIB (1-10 mSv; small to moderate risk level). The radiation risk is small compared to other nuclear and radiologic investigations, and is in the range of the annual background radiation from natural sources received by Dutch people (2 mSv/year).

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

- adult subjects (at least 18 years of age)
- primary aldosteronism with complete diagnostic work-up including succesfully performed adrenal venous sampling

Exclusion criteria

- diabetes melltus (type 1 or type 2)
- use of ketoconazole, metyrapone or cytostatic drugs in previous 6 months
- pregnancy
- severe contrast allergy
- serious comorbidities precluding surgery

Note: last 3 conditions are exclusion criteria for adrenal venous sampling, not for 11C-metomidate PET/CT

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not applicable
Generic name:	11C-metomidate

Ethics review

Approved WMO Date:	03-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-09-2010
Application type:	Amendment
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

ID: 28757
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-016056-48-NL
CCMO	NL28866.042.09
OMON	NL-OMON28757