The effect of intermittent sampling on aldosterone lateralisation during adrenal venous sampling (AVS) in patients with primary aldosteronism (PA)

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To study the variability of the lateralisation of the aldosterone/cortisol ratio*s when 3 instead of 1 sample is obtained and to study whether instantaneous measurement of cortisol during the procedure will prove to be advantageous.

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

Summary

ID

NL-OMON30899

Source
ToetsingOnline

Brief title
Effect of intermittent sampling on lateralisation during AVS

Condition

- Adrenal gland disorders

Synonym
Primary aldosteronism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adrenal venous sampling (AVS), Primary aldosteronism (PA)

Outcome measures

Primary outcome

The variation in lateralisation ratios (i.e. the concentration of aldosterone and cortisol in one adrenal vein compared to the concentrations in the other adrenal vein) at three different moments (t=0, t=15, t=30).

Secondary outcome

Evaluation whether determination of cortisol concentration during the procedure is advantageous.

Study description

Background summary

In patients with primary aldosteronism (PA) adrenal venous sampling (AVS) is performed to determine whether there is unilateral or bilateral adrenal hypersecretion of aldosterone. An accurate distinction between the unilateral and bilateral type is of utmost importance because patients with the unilateral type benefit from surgery whereas patients with bilateral PA are treated medically.
Because it is known that aldosterone secretion is rithmic, many medical expertise centres give ACTH before the AVS procedure to stimulate aldosterone secretion. The aim is to increase the accuracy of the procedure by stimulating aldosterone secretion: ideally, ACTH stimulates aldosterone secretion in the affected gland and not in the healthy contralateral gland (in unilateral adrenal pathology), or stimulates aldosterone secretion in both glands (in case of bilateral hyperplasia). However, a high-dose ACTH might also stimulate aldosterone production in the healthy contralateral gland which may lead to misinterpretation of AVS results with negative consequences for the patient; i.e. withholding surgery from a patient whose clinical situation might improve after adrenalectomy. In a recent study it was reported that a low-dose ACTH produced no effect at all. So currently it is unclear whether it is possible to

stimulate only an affected gland by ACTH, and if so, at which ACTH dose. Therefore, in this research proposal 3 intermittent samples are obtained, without prior ACTH. It is expected that, despite rithmic secretion, drawing 3 samples will result in at least 1 high result of aldosterone in these 3 samples.
In the regular AVS procedure cortisol concentrations are determined afterwards to confirm the successful placement of the catheter in the adrenal veins. In the unfortunate circumstance that cortisol concentration is low in one of the samples supposed to be obtained from an adrenal vein, the results cannot be interpreted and a second procedure is necessary. Instantenous measurement of cortisol during the procedure en recatheterisation in the same procedure if necessary, can prevent a second procedure.

Study objective

To study the variability of the lateralisation of the aldosterone/cortisol ratio*s when 3 instead of 1 sample is obtained and to study whether instantaneous measurement of cortisol during the procedure will prove to be advantageous.

Study design

This observational study will take place in the University Medical Centre Nijmegen, St. Radboud.
All patients with proven PA in whom, for diagnostic purposes, AVS is indicated are asked to participate in the study.
The *study* AVS procedure is different from the *regular* AVS procedure in that
*both adrenal veins are catheterized simultaneously (in stead of sequentially)
*2 extra samples are obtained after 15 and 30 minutes (extending the procedure with 30 minutes)
*cortisol is measured during in stead of after the catheterization
The study will last for one year, starting in November 2007. During this period we expect to include approximately 20 patients.

Study burden and risks

By investigating the difference in lateralisation ratio*s at three different moments we eventually hope to judge the AVS results more accurately and reliably select patients eligible for successful adrenalectomy. By analyzing cortisol during the procedure the patient might benefit whenever a second procedure is prevented.
The two extra samples will extend the procedure with 30 mintues. The regular AVS procedure involves a few small risks: i.e. occurrence of hematoma at the site of the femoral vein, trombosis, complications at the site of the adrenals and X-ray exposure. Participation in the study implicates that because of bilateral catheterization there is at both sites of the femoral veins a risk of

hematoma. Besides the, in the regular procedure, minimal risk of trombosis, is possibly somewhat higher because of the extension of the procedure with approximately 30 minutes. However, the effect of heparine (which is also adminstered in the regular procedure) lasts for a few hours.
In the regular and in the study procedure patients are exposed to X-ray examination for 20 minutes to obtain the first blood sample. Especially for the study procedure the patient is exposed two times extra (for 5 to 10 seconds) to X-ray examinations. In comparison to the 'standard' 20 minutes X-ray examination, this extra time is considered negligible.

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 with PA, in whom AVS is indicated

Exclusion criteria

Patients with increased risk of trombosis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL17698.091.07