Follow-up of patients with primary aldosteronism (PA): comparison of surgical and medical treatment

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In this study we want to investigate long-term follow-up of patients with PA. The outcome will be analyzed based on whether a decision to treat was guided by CT/MRI or AVS or both.

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

Summary

ID

NL-OMON32145

Source
ToetsingOnline

Brief title
Follow-up of patients with primary aldosteronism

Condition

- Adrenal gland disorders

Synonym
Conn syndrome, 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: Follow-up, Primary Aldosteronism

Outcome measures

Primary outcome

Course of blood pressure, medication and laboratory results after operation or

after start of PA specific medication (in the non-operated patients)

Secondary outcome

Differences in outcome based on whether a decision to treat was guided by

CT/MRI or AVS or both. Differences in outcome between operated and non-operated

patients.

Study description

Background summary

Primary aldosteronism (PA) is considered a frequent cause of hypertension. In PA hypertension is often found to be refractory to common antihypertensive drugs. Surgery has the potential to cure the disease with normalization of blood pressure without medication. However an adrenalectomy is only indicated in case of unilateral adrenal pathology; patients with bilateral adrenal pathology need to be treated medically. Therefore, an accurate distinction between the unilateral and bilateral type of PA is of utmost importance. Differentiation between both forms is usually done using imaging techniques such as CT/MRI or by means of adrenal venous sampling (AVS). However, results of CT/MRI and AVS are discordant in 41% of patients; e.g. unilateral pathology shown by CT/MRI whereas AVS indicates bilateral pathology, or vice versa, or unilateral pathology shown by CT/MRI whereas AVS indicates that the contralateral adrenal gland is affected. In general AVS is considered to be the gold standard to accurately differentiate between unilateral and bilateral adrenal pathology in PA and consequently, to accurately identify patients eligible for adrenalectomy or medical treatment. However, only detailed knowledge on long-term follow up results, in terms of severity of hypertension, use of medication(s) and improvement of biochemical parameters, can identify whether the decision to treat a patiënt with adrenalectomy has been legitimate.

To date, such detailed long-term follow up results are not available.

Study objective

In this study we want to investigate long-term follow-up of patients with PA.
The outcome will be analyzed based on whether a decision to treat was guided by CT/MRI or AVS or both.

Study design

Of all patients with PA, known in the UMCN St. Radboud, the medical file will be examined to gather medical data. The patients who underwent an adrenalectomy will be invited for a visit to the UMCN St. Radboud. During this visit standardized blood pressure measurements will be done and a venapuncture will be done to determine aldosterone, renin, potassium and creatinin.

Study burden and risks

For the operated patients who are not visiting the UMCN St. Radboud anymore, participation involves an extra visit to our hospital. There are no risks for the participating patients.

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 primary aldosteronism known in the UMCN St. Radboud in whom CT and/or MRI and/or AVS have been performed

Exclusion criteria

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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):	01-01-2008
Enrollment:	80
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	NL21121.091.07