Aldosterone-Renin Ratio to diagnose Primary Aldosteronism and a Tool to select Proper Antihypertensive Treatment. The Dutch ARRAT Study.

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With a standardized approach in a population with difficult to treat hypertension we want to explore how frequenty PHA is a cause of hypertension and what the test characteristics of the aldosterone-renin ratio are. Additionally we want to...

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

Summary

ID

NL-OMON31604

Source
ToetsingOnline

Brief title
The Dutch ARRAT Study

Condition

- Adrenal gland disorders
- Vascular hypertensive disorders

Synonym
morbus Conn, Primary aldosteronism

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nierstichting Nederland,Pfizer

Intervention

Keyword: aldosterone-renin ratio, aldosteronism, eplerenone, Hypertension

Outcome measures

Primary outcome

Primary endpoints are 1) the test characteristic of the aldosterone-renin ratio

in a population of difficult to treat hypertensive subjects and 2) determinants

of the blood pressure response to an aldosterone receptor antagonist.

Secondary outcome

Secondary endpoints are 1) the prevalence of PHA in a Dutch population of

difficult to treat hypertension, 2) the influence of antihypertensive therapy

on the aldosterone-renin ratio and 3) the concordance between the intravenous

and oral salt loading test.

Study description

Background summary

Primary aldosteronism (PA) is characterized by an autonomous production of aldosterone by the adrenal gand, almost always resulting in a moderate to severe rise in blood pressure, a suppressed plasma renin activity and sometimes hypokalemia. To establish the diagnosis of PHA is important for two reasons. First, this condition requires specific treatment, and second it is associated with an increased risk of cardiovascular disease as compared to essential hypertension. Owing to the frequent use of the aldosterone-renin ratio as a screening test, PHA appears to be an unexpected frequent cause of hypertension. In The Netherlands systematic screening of PHA does not take place and the way the diagnostic tests are performed in hospitals is variable.

Study objective

With a standardized approach in a population with difficult to treat hypertension we want to explore how frequenty PHA is a cause of hypertension and what the test characteristics of the aldosterone-renin ratio are. Additionally we want to investigate the determinants of the aldosteron-renin ratio and explore whether this ratio predicts the blood pressure response to an aldosterone receptor antagonist.

Study design

In a multicentric study patients with difficult to treat hypertension undergo a diagnostic and a therapeutic traject. In each patient the aldosterone-renin ratio is measured two times while patients use their own antihypertensive medication. Beta-adrenergic-receptor blocking agents and potassium-sparing diuretics are forbidden. The ratio is repeated after the patients have been treated with antihypertensive combination therapy that does not influence the aldosterone-renin ratio. All patients are subjected to an intravenous (gold standard) and oral salt loading test. subsequently patients are treated for 3 months with an aldosterone receptor antagonist added to their usual antihypertensive medication. The blood pressure response to the aldosterone-receptor blocker will be related to the aldosterone-renin ratio.

Intervention

Treatment for 3 months with eplerenone, 50 mg once daily.

Study burden and risks

The burden of the patients is mainly time investment (6 to 7 hours during a study period of 38 weeks). The risk is low. All tests applied are standard procedures. Eplerenone that is used in the therapeutic phase of the study is registered in the Netherlands as highly selective aldosterone receptor antagonist for the treatment of chronic cardiac failure.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Refractory hypertension
Men and women (non-pregnant)
Age 18-60 yrs
BMI < 32 kg/m2

Exclusion criteria

Known cause of hypertension
White coat hypertension
Severe renal failure
BMI >32 kg/min
Stroke or myocardial infarction within the last 6 months

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2009
Enrollment:	500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Inspra
Generic name:	Eplerenone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	19-04-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-006618-13-NL
ClinicalTrials.gov	NCT00407784
CCMO	NL11725.078.06