Redistribution of renal flow and tubular inflammation

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The main goal of the study is evaluation of the effects from renal artery stenosis on intrarenal flow-distribution and tubular function. Assumed and measured effects are alterations of medullary flow, inflammatory markers and overall tubular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON30683

Source
ToetsingOnline

Brief title
Redistribution of renal flow and tubular inflammation

Condition

- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
occlusion of the renal artery, Renal artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Inflammation, PTRA, Renal artery stenosis, Renal deterioration

Outcome measures

Primary outcome

Intrarenal hemodynamics (calculated from MRI signal-time curves and renal

inulin/PAH clearance) and tubular damage (markers in the urine).

Secondary outcome

Renal and cardiovascular indices used in common clinical practice.

Study description

Background summary

Renal artery stenosis is a common cause of secondary hypertension, which is associated with progressive renal decline and an increased cardiovascular risk. The critical element promoting hypertension in this disorder is a reduced arterial perfusion to the post-stenotic kidney, which initiates the Renin-Angiotensine-Aldosteron system and increases efferent arteriolar resistance. Although, an causal association between decreased renal blood flow and renal functional decay is clinically well-accepted, recent research indicated that alteration of intrarenal hemodynamics and ensuing renal damage are not explained by a globally decreased renal blood flow per se. Hypothesis: Alteration in the intrarenal flow-distribution may precede overt renal deterioration and results in a decreased peritubular capillary flow, decreased tubular oxygen supply and tubulo-interstitial inflammation.

Study objective

The main goal of the study is evaluation of the effects from renal artery stenosis on intrarenal flow-distribution and tubular function. Assumed and measured effects are alterations of medullary flow, inflammatory markers and overall tubular function.

Study design

Longitudinal study design with 9 months follow-up after PTRA, which compares the intrarenal effects of clinical treatment in patients with hemodynamically

significant unilateral artery stenosis.

Study burden and risks

Participating patients won*t obtain direct benefits, but results from the study could influence future clinical treatment decisions. Participation requires three site visits (total time spent in research facility: 12-15 hours), all three visits are preceded by a pharmacological wash-out (first visit: 3 weeks; second visit 9 days; third visit 9 months after PTRA: 3 weeks) and salt-restriction during seven days (before all three visits; total duration of salt restriction 21 days in 9 months). During each visit a maximum of 60mL of blood will be drawn (sampling from venous line, 6 samples of 10mL) for measurement of renal inulin/PAH clearance and characterisation of biochemical risk factors. Moreover, an intrarenal flow distribution will be assessed using a dynamic MRI. Although MRI is a safe and non-invasive technique, the intravenous administering of gadolinium contrast has been associated with a small risk of contrast induced nephrotoxicity (< 1%).

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

- Scheduled PTRA, which procedure is clinically indicated by the presence of angiographically proven, symptomatic unilateral renal artery stenosis of >50% luminal diameter reduction.

Exclusion criteria

- Recipients of a renal transplant, primary renal diseases or nephrectomy.
- Bilateral renal artery stenosis.
- Fibromuscular dysplasia.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	19-03-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-10-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-02-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL15855.068.06