Autonomic and cardiac function in end stage renal disease patients: A pilot study

Published: 10-12-2012
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The main objective of this pilot study is to determine the effects of vascular access construction on autonomic and cardiac function.

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37476

Source
ToetsingOnline

Brief title
Autonomic and cardiac function in end stage renal disease patients.

Condition

- Heart failures
- Renal disorders (excl nephropathies)
- Vascular therapeutic procedures

Synonym
autonomic function, heart function

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Máxima Wetenschapsfonds;de

subsidieaanvraag is goedgekeurd.

Intervention

Keyword: Autonomic function, Cardiac function, End stage renal disease, Haemodialysis access

Outcome measures

Primary outcome

- Autonomic function

o The following measurements are made in rest:

o heart rate variability (HRV),

o blood pressure variability (BPV) and

o baroreflex sensitivity (BRS).

o Respiratory sinus arrhythmia (RSA) is determined during the deep breathing

test.

o During the vasalva manoeuvre the following measurements are made:

o vasalva ratio (VR) and

o blood pressure respons to the vasalva manoeuvre.

o Blood pressure and heart rate response to the supine-to-stand-test.

Secondary outcome

- Cardiac function measured using echocardiography

- Blood serum levels of several heart markers

- Score on the Hand Ischemic Questionnaire (HIQ).

- Score on the Minnesota living with heart failure questionnaire (Minnesota).

- Successful AVF maturation

- Mortality

- Morbidity

Study description

Background summary

Heart failure is a commonly occurring complication in haemodialysis (HD) patients who have an arteriovenous fistula (AVF)(1-3). It is unknown whether a *portion* of the heart failure is caused by the extra burden of an open AVF. It is reasonable to suggest that the hemodynamic effects of an AVF with a large flow (HFA, high flow acces, > 2 L/min access flow) are greater compared to a small flow AVF.

The number of diagnostic tools quantifying the systemic hemodynamic effects of an AVF on cardiac capacity are limited. Some have suggested that the effect of manually compressing the AVF may provide important information. If the AVF is occluded, a baroreflex mediated bradycardia is supposed to occur if the fistula indeed has a significant contribution to systemic hemodynamics.

Interestingly, we have recently found that both patients with a normal flow AVF and with a HFA showed a significant decrease in heart rate after manual AVF occlusion. In contrast, only HFA patients demonstrated a significant increase in both systolic and diastolic blood pressure after AVF occlusion whereas patients with normal flow AVF*s did not. Findings of our study suggest that baroreflex function is disturbed in HFA patients (but not in normal flow patients) as they do not sufficiently adapt to the increased blood pressure by lowering the heart rate.

We hypothesise that autonomic function is negatively influenced by an AVF. This mechanism may possibly contribute to an excess mortality risk in HD patients.

Study objective

The main objective of this pilot study is to determine the effects of vascular access construction on autonomic and cardiac function.

Study design

An pilot study will be conducted to evaluate the effect of AVF construction on short term cardiac and autonomic function.

Study burden and risks

The burden of participation is minor as patients are examined three times in six months while lying on a bed. Only a small of blood is drawn. Unfortunately the patients may suffer a vasovagal collaps during one of the tests.

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

All patients with chronic kidney disease (CKD) stage five who are in a pre-dialysis course and planned for an AVF construction are included in the intervention group.

Exclusion criteria

1. chronic atrial fibrillation or
2. frequent ventricular premature beats,
3. grade III or IV heart failure (according to the NYHA),
4. with permanent pacemakers,
5. previous vascular access (AVF, graft or venous-catheter) or PD catheter,
6. impaired mental capacity or language barrier.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	10-12-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL39052.015.12