Contrast echocardiography and vortex imaging in patients with left ventricular assist devices; single-center observational prospective study into detection of intracardiac thrombosis

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

Summary

ID

NL-OMON43399

Source
ToetsingOnline

Brief title
CE-VAD STUDY

Condition

- Heart failures

Synonym
bloodclotting, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contrast, LVAD, Thrombosis

Outcome measures

Primary outcome

The presence of intracardiac thrombus will be assessed on the standard and contrast-enhanced echocardiographic images. Intracardiac flow pattern will be analysed using Tomtec Hyperflow software. A follow-up study will be performed to evaluate the echo contrast and vortex imaging parameters and incidence of thrombosis and outcome of thromboembolic events.

Secondary outcome

NA

Study description

Background summary

Left ventricular assist devices (LVAD*s) have been increasingly become an important therapeutic option of end-stage heart failure. However, pump thrombosis (PT) and/or thromboembolic events (TE) defined as ischemic stroke and transient ischemic attacks, remain life-threatening complications. Thromboembolic events including ischemic stroke, and acute pump thrombosis rate varied between 1 and 13.9% among different studies of continuous flow LVAD's with either axial or centrifugal flow. Unrecognized LV thrombus at the time of LVAD implantation could be trapped into a LVAD and results in pump dysfunction, haemolysis, pump thrombosis, stroke, or peripheral embolism. There is currently no golden standard in detection of intra cardiac or pump related thrombi in LVAD patients due to suboptimal imaging of the cavities, inflow and outflow cannula. However, early detection of these thrombi could help in the proper management of these LVAD patients.

Contrast echocardiography (CE) is increasingly used in LV opacification and endocardial border definition in patients with technically suboptimal echocardiograms. Current literature is however, scarce in use of contrast agents in LVAD patients, In a small sample of LVAD patients undergoing clinically indicated echocardiography, CE was feasible and safe with improved image interpretation. Furthermore, intraventricular blood flow dynamics could be better detected with use of vortex imaging, by using particle image velocimetry (PVI) in case of suboptimal imaging. Recent studies with PVI in acute myocardial infarction are very promising. This technology has yet to be validated for LVAD patients. In our study, we would like to evaluate the clinical use of these early detection methods in patients with continuous flow LVADs(cf-LVADs) devices.

Study objective

The primary objective of this study is to identify in which imaging modality, including CE and vortex imaging, could help us in the early diagnoses of intracardiac thrombosis in LVAD patients. We attempt to provide a more dedicated method for the early detection of thrombosis in LVAD.

Study design

Single-center prospective observational study

Study burden and risks

Patients will receive ultrasound contrast agent through an intravenous infusion. The echo contrast study takes approximately 30 minutes. Patients will be invited to participate and with permission of the patient clinical data from the clinical interview and physical examination may be retrieved from the medical files. The study is an observational diagnostic study, physical and physiological discomfort for the patients is very limited. The ultrasound contrast agent is safe and registered for the routine clinical use in echocardiography.
There is a small risk of an allergic reaction after administration of ultrasound contrast agent (0.01%).17 During all examinations a medical doctor will be present to react immediately in case of an allergic reaction. Additional blood tests will not be required. The risks associated with participation can be considered negligible and the burden can be considered minimal.

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

> 18 years-old
Patient with LVAD
Written informed consent

Exclusion criteria

- Refusal to participate in the study or unable to give consent.
- Unstable clinical symptoms
- Known allergy for contrast-enhanced ultrasound agents, including SonoVue.
- Pregnancy
- Breastfeeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-06-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2016
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
CCMO	NL56507.078.16