The effect of implementation of a ramp test to optimize LVAD pump speed on clinical and echocardiographic outcomes.

Published: 20-05-2014
Last updated: 20-04-2024

The objective of the current study is to assess the effect of speed optimization on clinical and echocardiographic parameters at 3 months follow-up.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON41197

Source
ToetsingOnline

Brief title
LVAD pump speed optimalisation

Condition

- Heart failures

Synonym
heart failure, left ventricular mechanical assistance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Clinical functioning, Echocardiografic functioning, LVAD pump speed, Optimalization test

Outcome measures

Primary outcome

The effect of pump speed optimizing on clinical (including NYHA class, pro-BNP,

quality of life assessment, 6 minute walking test and bicycle test) and

echocardiographic parameters at 3 months follow-up.

Secondary outcome

Not applicable.

Study description

Background summary

Left ventricular mechanical assistance is the ultimate treatment option in patients with end stage heart failure ineligible for transplant. A left ventricular assist device (LVAD) is a pump that is connected to the left ventricle and the aorta via an inflow and outflow cannula. The pump supports the heart by withdrawing blood from the left ventricle and delivering it directly into the aorta. Thereby, end-organ perfusion is improved.

The prognosis and clinical performance of patients with a left ventricular assist device (LVAD) as destination therapy are strongly determined by the remaining cardiac function. The speed of the LVAD pump influences the intrinsic cardiac function by decompressing the left ventricle. An inadequately low speed (rotations per minute) can result in left ventricular overload and mitral valve insufficiency, while an increased speed may lead to a suction cascade with leftward deviation of the interventricular septum, obstruction of the inflow cannula, dilatation of the right ventricle and severe tricuspid regurgitation. Within the normal speed range of the pump the septum is in midline position between the two ventricles and the aortic valve opens partly as a result of adequate left ventricular filling status and contraction. It is unknown whether further adjustments of the pump speed within the approved range can improve cardiac performance and clinical outcomes. Recently Uriel et al. presented the Columbia Ramp Study in which they performed 52 speed optimization test in LVAD

patients with a HeartMate II device and corrected the device speed in 61% of the patients, showing the clinical value of speed optimization. Follow-up data of these patients were however not presented in the article.

In our centre speed settings are routinely assessed with a ramp test during implantation in the operating room as well as in the immediate post-operative phase. For this purpose the hemodynamic performance at different pump speeds is assessed with the use of echocardiography after which the most optimal setting is chosen. After discharge follow-up echocardiography is performed according to the mission! LVAD protocol (Fig 2). At these follow-up visits, in some patients it is noted that long-term unloading of the left ventricle alters the ventricular geometry and function. Furthermore, as a consequence of LVAD implantation exercise capacity increases which requires an increased cardiac output. In this situation patients may potentially benefit from echocardiographically re-evaluation of the different pump speed settings. For this purpose, the ramp test routinely performed in the operating room and in the immediate post-operative phase could be repeated. In the current study we hypothesize that optimization of the pump speed to the ambulatory situation improves clinical and echocardiographic performance at 3 months follow-up.

Study objective

The objective of the current study is to assess the effect of speed optimization on clinical and echocardiographic parameters at 3 months follow-up.

Study design

The design is a prospective cohort study in which LVAD patients will function as their own control over time.

Time frame:
1 month: Informing patients
3 months: Enrolling patients and baseline measurements
3 months: Follow-up measurements
3 months: Data analysis and writing article

Intervention

Study patients will undergo adjustments to the pump speed of the HVAD. The HVAD has an European Commercial approval since January 2009. Normal pump speed recommended by the manufacturer is between 2400 and 3200 RPM (the motor speed range is between 1800 and 4000 RPM). In the current study different pump speeds within these limits will be assessed at baseline to determine the optimal speed based on echocardiographic findings. The optimal pump speed will be maintained for 3 months followed by clinical and echocardiographic re-evaluation of

performance.

Study burden and risks

All measurements will be performed during routine follow-up visits. Adjacent to the routine examinations according to the Mission! LVAD protocol, at one moment an extra echocardiography with additional images will be achieved, as well as one extra quality of life assessment, 6 minute walking test and bicycle test. These additional examinations will take approximately 2 hours.
No additional risk is expected from participation in this study as the optimization protocol shows resemblance to the routinely performed pump speed assessment in the post-operative phase on the intensive care unit. Pump speed optimization will be performed within the normal speed range recommended by the manufacturer.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- The subject is 18 years or older
- The subject must have a HeartWare Ventricular Assist Device (HVAD) implanted as destination therapy in the LUMC.
- The subject must be in a hemodynamically stable condition.

Exclusion criteria

A potential subject will be excluded if he or she does not meet the inclusion criteria at the moment of inclusion or during the studied period.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2014
Enrollment:	0
Type:	Actual

Medical products/devices used

Generic name:	Left Ventricular Assist Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-05-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL48374.058.14