A combined transvenous and epicardial lead placement procedure for implantation of cardiac resynchronization devices: a feasibility study

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To assess the feasibility of implantation of CRT devices via a combined transvenous and epicardial procedure in patients with an unfavourable coronary venous anatomy. In addition, the safety of the procedure will be assessed in preparation for a...

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

Summary

ID

NL-OMON40512

Source
ToetsingOnline

Brief title
Combined transvenous and epicardial lead placement for CRT

Condition

- Heart failures

Synonym
Heart failure, pump failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Epicardial, Heart failure, Intraventricular conduction delay

Outcome measures

Primary outcome

Number of succesful device implantations.

The procedure is considerd succesfol when implantation of a CRT device succeeds

in all study patients through the procedure described above.

Secondary outcome

1. Safety.

The procedure is considerd safe when no procedure related deaths occur and

procedure related complications occur in three patients or less.

2. Conversion to minithoracotomy.

Study description

Background summary

At least thirty percent of patients undergoing transvenous implantation of a device for cardiac resynchronization therapy (CRT) do not respond to therapy. Possible causes include failure of left ventricular lead placement due to an inaccessible coronary sinus and suboptimal left ventricular lead position or dislocation. These problems can be overcome by epicardial implantation of the left ventricular lead using video-assisted thoracic surgery (VATS).

Study objective

To assess the feasibility of implantation of CRT devices via a combined transvenous and epicardial procedure in patients with an unfavourable coronary venous anatomy. In addition, the safety of the procedure will be assessed in preparation for a larger randomized study.

Study design

Single centre, prospective cohort feasibility study, not placebo controlled.

Intervention

All patients undergo implantation of a CRT device via a combined transvenous and epicardial approach.

Study burden and risks

CRT implantation already has a class IA indication in the selected study population. When effective, symptoms and prognosis improve significantly. The implantation of the right atrial and right ventricular leads will be performed via the transvenous route according to standard procedure. No additional risks or benefits accompany this part of the procedure. The left ventricular lead will be implanted epicardially using VATS through a standardized procedure already used in 70 patients in which transvenous placement of the left ventricular lead failed. Benefits are a 100% chance of success of adequate left ventricular lead placement with a 0% lead failure rate (current status in the UMCG), reduced radiation exposure, smaller risk of cardiac tamponade, shorter procedure time, no risk of coronary sinus rupture and reduced need for re-intervention. Associated burdens are the necessity to undergo general anesthesia, chest tube drainage for at least a day, a greater need for postprocedural pain medication and longer hospital stay (a few days). VATS associated complications include lung trauma, pneumothorax, peri- and postprocedural bleeding and infection. However, pneumothorax, bleeding and infection are also complications of transvenous lead placement. Both epicardial and transvenous lead placement carry a risk of ventricular arrhythmias.

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

1. Left ventricular ejection fraction < 36%.
2. Intraventricular conduction delay >119 ms of >129 ms and presence of left bundle branch block.
3. On optimal medical therapy for heart failure.
4. No sidebranch of the coronary sinus near the posterolateral wall of the left ventricle and/or presence of a Thebesian valve which reduces coronary sinus diameter 50% or more (corresponding to a decrease in cross sectional area of 75% or more).
5. Signed informed consent.

Exclusion criteria

1. Previous intrathoracic surgery
2. Coronary ischemia or recent myocardial infarction (< 6 months)
3. Suspected presence of a non-compliant left lung.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	CRT devices
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL46451.042.13