Optimal patient Selection for CArdiac Resynchronisation Therapy using Molecular Imaging

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To determine the (added) value of molecular imaging parameters for selecting patients that will benefit from CRT, specifically:-Phase standarddeviation-Summed infarct score-Innervation Heart/Mediastinum ratio

Ethical review	Approved WMO
Status	Will not start
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON38477

Source
ToetsingOnline

Brief title
SCART-MI

Condition

- Heart failures

Synonym
heart failure, Left ventricular dyssynchrony

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: GE Healthcare,onderzoeksgrant voor de kosten van de onderzoeksmiddelen

Intervention

Keyword: cardiac resynchronisation, heart failure, MIBG-imaging, myocardial perfusion scintigraphy

Outcome measures

Primary outcome

-99mTc-Tetrofosmin(MPS)-based dyssynchrony and infarct burden measurements

-123I-metaiodobenzylguanidine(MIBG)-based Heart-to-Mediastinum(H/M)-ratio

The main study parameters will be compared to response to CRT as defined by:

-Reduction in LVESV * 15%.

Secondary outcome

-change in innervation and perfusion parameters after CRT

-Infarct location as predictor of respons to CRT

Study description

Background summary

Rationale: Cardiac resynchronization therapy (CRT) is an effective therapy for heart failure patients with electromechanical ventricular dyssynchrony. Optimization of selection criteria is necessary as with the current criteria up to a third of patients undergoing this costly and invasive therapy do not benefit from it.
We hypothesize that adding selection criteria based on molecular imaging techniques (i.e. parameters of myocardial perfusion and myocardial sympathetic activity) can further help distinguish responders from non-responders.

Study objective

To determine the (added) value of molecular imaging parameters for selecting patients that will benefit from CRT, specifically:
-Phase standarddeviation
-Summed infarct score

-Innervation Heart/Mediastinum ratio

Study design

Prospective single center non-randomised study with non-invasive measurements (Pilot).

Study burden and risks

99mTc-Tetrofosmin myocardial perfusion imaging (MPI) is standard-of-care for CRT patients to identify infarct size and location. The added measurements are post-processing only and do not pose any additional burden on the patient.
123I-MIBG myocardial sympathetic nerve activity imaging (MIBG) will be added in a single-acquisition-study dual-isotope imaging design, adding approximately 3 hours and 2.4 milliSievert (mSv) of radiation burden to the study, as opposed to more than 4 hours on another day in a standard dual-timepoint imaging design, minimising the time burden for the patient.
There is no direct benefit for the patient from these measurements. However, the results of the study may benefit all future CRT patients by better identifying responders and minimising the amount of unnecessary CRT-device implantations.

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

-Informed consent obtained
-Chronic heart failure;
-New York Heart Association functional class II, III or IV;
-QRS duration *150 ms for NYHA class II or *120 ms for NYHA class III/IV;
-Optimal pharmacological therapy;
-Left ventricular ejection fraction *35%.

Exclusion criteria

-Contraindications for implantation of a CRT device;
-Age <18 years or incapacitated adult;
-Pregnancy;
-Severe aortic stenosis with a valve area or aortic valve replacement in history;
-Known allergic reaction to iobenguane;
-Participation in another clinical study that prohibits any procedures other than standard.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	91

Type:	Anticipated

Ethics review

Approved WMO Date:	08-07-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL42949.041.12