Postoperative Hemodynamic Effects of Cardiac Resynchronisation Therapy in Cardiac Surgery Patients with Impaired Left Ventricular Function

Published: 25-04-2007
Last updated: 08-05-2024

To investigate if the intraoperative biventricular pacing can improve the hemodynamic performance and decrease the need of mechanical and pharmacological support.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON31347

Source
ToetsingOnline

Brief title
Resynchronisation in Cardiac Surgery (PHECRET study)

Condition

- Heart failures

Synonym
Biventricular pacing, Resynchronisation Therapy

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting R&D Cardiothoracaal chirurgie

Catharina Ziekenhuis

Intervention

Keyword: Cardiac Surgery, Left Ventricular Dysfunction, Resynchronisation Therapy

Outcome measures

Primary outcome

Changes in left ventricular pressures after biventricular pacing in comparison

with the patient*s own rhythm and right ventricular pacing.

Secondary outcome

Perioperative changes in hemodynamic performance and need for mechanical and

pharmacological support after biventricular pacing.

Study description

Background summary

Cardiac resynchronization Therapy (CRT) can acutely improve cardiac performance as expressed by increased pulse pressure and LV dP/dt max. Moreover, cardiac function improves at diminished energy costs. Implementing CRT during and after cardiac surgery could improve hemodynamics and lessen the need for inotropic medication.

Study objective

To investigate if the intraoperative biventricular pacing can improve the hemodynamic performance and decrease the need of mechanical and pharmacological support.

Study design

A prospective mono-center study.

Study burden and risks

There is no extra risk for the patients by insertion of a pacemaker lead or

measuring the hemodynamic data intra and postoperatively.

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

• Age of 18 years or more.
• Patients scheduled for coronary artery bypass grafting surgery (CABG) and/or valve surgery.
• Left ventricular ejection fraction (EF) of 35% or less.
• Sinus rhythm with one of the following criteria:
1. QRS duration of > 130 ms and left bundle branch pattern
2. Pacemaker dependent patients with right ventricular paced rhythm and QRS width of > 180 ms, or
3. Evidence of left ventricular dyssynchrony with Tissue Doppler Imaging (TDI)

• Able to give informed consent.

Exclusion criteria

Myocardial infarction within the past 3 months

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2007
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-04-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL17161.060.07