

Comparison of Mid-term effects of Pacing from Right ventricular Outflow STimulation with apical and combined right ventricular pacing.

Published: 24-03-2009

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To assess whether pacing from the right ventricular outflow tract, the right ventricular apex or combined pacing shows difference in right and left ventricular ejection fraction and asynchrony.

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON32441

Source

ToetsingOnline

Brief title

Extended PROUST study

Condition

- Cardiac arrhythmias

Synonym

chronic right ventricular pacing, pacemaker dependancy

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Wetenschapsfinanciering maatschap nucleaire Geneeskunde St. Antonius Ziekenhuis Nieuwegein

Intervention

Keyword: gated blood-pool SPECT, pacing, right ventricular outflow tract

Outcome measures

Primary outcome

This is an observational study in a limited population of patients previously included in the PROUST study, to assess the feasibility of the quantitative blood-pool SPECT. The study is designed as proof of principle that QRS duration and cardiac functioning in RV paced patients are related.

Secondary outcome

not applicable

Study description

Background summary

Ventricular pacing is an accepted therapy for patients with brady-arrhythmia. Conventionally the ventricular pacing lead is placed in the right ventricular apex (RVA). However, recent data suggest that pacing in this site can arouse adverse effects on left ventricular function (LVF) and prognosis of the paced patient. Because of a supposed more physiological activation of the left ventricle right ventricular outflow tract (RVOT) pacing has been introduced. The PROUST study was designed to investigate the effects of RVA, RVOT and RVA/RVOT combined (RVC) pacing on echocardiographically determined LVF, QoL and walking distance in patients with spontaneous or induced AV block with chronic atrial fibrillation. This study showed no differences after a 2 month cross-over period

Study objective

To assess whether pacing from the right ventricular outflow tract, the right ventricular apex or combined pacing shows difference in right and left

ventricular ejection fraction and asynchrony.

Study design

All patients will undergo gated blood-pool SPECT to assess LV and RV volume, LVEF, RVEF, interventricular and LV intraventricular mechanical delay as well as phase analysis of both ventricles will be measured by gated blood-pool SPECT. Images will be acquired during pacing from the RVA, RVOT and RVC.

Study burden and risks

one outpatient clinic visit, during which blood-pool SPECT imaging will be performed

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

participation in PROUST study

Exclusion criteria

not applicable

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Will not start

Enrollment: 20

Type: Anticipated

Ethics review

Not approved

Date: 24-03-2009

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	NL24566.100.08