Optimal Antitachycardia Therapy in ICD Patients without Pacing Indications

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON30671

Source
ToetsingOnline

Brief title
Study code: ITAC03
Study name: OPTION Study

Condition

- Cardiac arrhythmias

Synonym
cardiac arrest, heart rhythm disorders

Research involving
Human

Sponsors and support

Primary sponsor: ELA Medical
Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: AAISafeR pacing mode, Antitachycardia Therapy, Implantable Defibrillator (ICD), Slow VT

Outcome measures

Primary outcome

The primary objective of this study is to evaluate the clinical outcome of dual-chamber ICD therapy with minimized ventricular pacing compared with single-chamber device therapy with settings which are common in clinical practice. The outcome measure is the number of inappropriate shock therapy and a combined end point of all-cause mortality, hospitalisation for specified cardiac reasons (CHF, symptomatic AF, cardioversions for AF*, stroke, under-detected VT) and. Refer to 3.2.1 paragraph for more details.
It is hypothesized that rate for unwanted clinical events is lower in the dual-chamber group than in the single-chamber group. In detail: the number of inappropriate shock therapies is lower in the dual-chamber arm but the rate of all cause mortality, hospitalisation for cardiac reasons as specified above is equal for both groups.

Secondary outcome

1. all cause mortality and cardio-vascular related mortality

2. Report Hospitalizations due to cardio-vascular event (specified for each type of event)

3. Report time to first occurrence of inappropriate ICD shock therapy

4. Evaluation of the impact of the different therapies on quality of life and heart failure status

5. Report sensitivity and specificity for the applied VT/SVT discrimination for the first 100 patients in each group who complete their 27 months follow up with a demonstrated correct pacing/sensing functioning

6. Report the inappropriate overall device reactions defined by inappropriate shock and/or ATP therapy or inappropriate therapy delay/inhibition > 2 minutes

7. Report the time to first documented occurrence of permanent or persistent AF* and number of patients moving into permanent AF

8. Report the cardiac dimensions obtained via echocardiography for a subset of patients of both study groups at baseline and after 27 months

9. Report Slow VT incidence

10. Report unscheduled visits and hospitalizations due to slow VT

11. Report system-related complications (see section 2.3.9 for definition)

12. Report the mean and median cumulative percentage of ventricular pacing for both study groups, and the % of pats with <1% V pacing.

13. Report the overall success rate of ATP in the FVT zone

14. Describe the cost-effectiveness for both study groups

15. Determination of the PPV and NPV for Tvar risk stratification to identify patients at risk to develop VT/VF during follow up for the overall study population.

Study description

Background summary

This study evaluates the impact of a new pacing mode avoiding unnecessary ventricular stimulation in combination with advanced dual chamber detection

with slow VT management on the clinical outcome for hospitalization and mortality and inadequate therapy in medically stable, ICD-indicated patients with impaired left ventricular function (LVEF <= 40%) who do not have pacing indications and no indication for Cardiac Resynchronization Therapy (CRT). It compares a new pacing mode avoiding ventricular stimulation when not needed combined with dual chamber detection with a pure ventricular back up pacing and single chamber detection criteria with pure ventricular back up pacing. Therapies are compared in a prospective, randomized, single-blinded, parallel trial with a 24-month randomized treatment period. Randomization follows a 1:1 ratio. ICD therapy is enabled for all patients throughout the study. All patients receive optimal drug therapy for arrhythmia and heart failure treatment.

Study objective

Primary study objective:
The primary objective of this study is to evaluate the clinical outcome of dual-chamber ICD therapy with minimized ventricular pacing compared with single-chamber device therapy with settings which are common in clinical practice.
The outcome measure is the number of inappropriate shock therapy and a combined end point of all-cause mortality, hospitalisation for specified cardiac reasons (CHF, symptomatic AF, cardioversions for AF*, stroke, under-detected VT)
It is hypothesized that rate for unwanted clinical events is lower in the dual-chamber group than in the single-chamber group. In detail: the number of inappropriate shock therapies is lower in the dual-chamber arm but the rate of all cause mortality, hospitalisation for cardiac reasons as specified above is equal for both groups.
Secondary study objectives are:
1. all cause mortality and cardio-vascular related mortality
2. Report Hospitalizations due to cardio-vascular event (specified for each type of event)
3. Report time to first occurrence of inappropriate ICD shock therapy
4. Evaluation of the impact of the different therapies on quality of life and heart failure status
5. Report sensitivity and specificity for the applied VT/SVT discrimination for the first 100 patients in each group who complete their 27 months follow up with a demonstrated correct pacing/sensing functioning
6. Report the inappropriate overall device reactions defined by inappropriate shock and/or ATP therapy or inappropriate therapy delay/inhibition > 2 minutes
7. Report the time to first documented occurrence of permanent or persistent AF* and number of patients moving into permanent AF
8. Report the cardiac dimensions obtained via echocardiography for a subset of patients of both study groups at baseline and after 27 months
9. Report Slow VT incidence
10. Report unscheduled visits and hospitalizations due to slow VT
11. Report system-related complications (see section 2.3.9 for definition)

12. Report the mean and median cumulative percentage of ventricular pacing for both study groups, and the % of pats with <1% V pacing.
13. Report the overall success rate of ATP in the FVT zone
14. Describe the cost-effectiveness for both study groups

Study design

After admitting the patients to the study, this by checking the in-and exclusion criteria and the informed consent given by the patient, the patient will be randomised before implant to the optimal treatment group (AAIsafeR 60 plus dual chamber detection with a TDI set to 500 ms and at least ATP activated) or control group (VVI 40 plus optimized single chamber detection with at least a monitoring detection zone TDI set to 500 ms). Programming of therapies and an additional detection zone is left to physicians choice.

Study burden and risks

Normal risks associated with the implant of an implantable defibrillator.

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. Patient has been prescribed the implantation for an ICD system accordingly to the relevant currently-approved ACC/AHA guidelines1 (Appendix L) or ESC guidelines35 (Appendix M) or any relevant currently-approved local guidelines for the implantation of an ICD-system
2. Impaired left ventricular function demonstrated by a left-ventricular ejection fraction (LVEF) <= 40 %, measured by angio-scintigraphy, echocardiography, or contrast ventriculogram.
3. An optimal (as determined by the enrolling physician) medical regimen.
4. Patient has received all relevant information on the study, and has signed and dated a consent form.

Exclusion criteria

1. Any generally accepted indication for standard cardiac pacing, or any contraindication for standard cardiac pacing.
2. Any indication for CRT accordingly to the relevant currently-approved ACC/AHA1 (Appendix L) or ESC35 (Appendix M) guidelines for the implantation of a CRT system.
3. Any contraindication for ICD therapy and the implant of a dual chamber ICD.
4. ICD replacement
5. Chronic atrial arrhythmias or cardioversion for atrial fibrillation within the past month.
6. A PR interval > 250 ms or AR interval > 300 ms measured at implant.
7. Hypertrophic obstructive cardiomyopathy.
8. Acute myocarditis.
9. Unstable coronary symptoms or myocardial infarction within the last month.
10. Recent (within the last month) or planned cardiac revascularization or coronary angioplasty.
11. recently performed (in the last month) or planned cardiac surgery
12. Already included in another clinical study.
13. Life expectancy less than 24 months.
14. Inability to understand the purpose of the study or refusal to cooperate.
15. Inability or refusal to provide informed consent and, if not part of the informed consent, a Health Insurance Portability and Accountability Act (HIPAA) authorization.
16. Unavailability for scheduled follow-up at the implanting or cooperating center.
17. Age of less than 18 years.
18. Pregnancy

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Implantable Cardio Defibrillator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

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	NL15693.067.06