ENHANCED device programming to reduce therapies and improve quality of life in Implantable Cardioverter Defibrillator patients: A prospective, single-arm safety monitoring study

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Primary objective:• To investigate whether Enhanced programming is safe for primary and secondary prevention patientsSecondary objectives:• Investigate the impact of Enhanced programming on adverse events (related to ICD shock with consequences and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON39945

Source
ToetsingOnline

Brief title
ENHANCED-ICD study

Condition

- Cardiac arrhythmias

Synonym
cardiomyopathy, disorder of the heart muscle

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: een grant van Medtronic

Intervention

Keyword: ICD programming, quality of life, safety

Outcome measures

Primary outcome

The primary study outcome is safety of Enhanced programming within 12 months after implantation (combined endpoint): all arrhythmic syncopes and other intervention-related safety events (either hospitalization, death or other serious adverse event due to Enhanced programming.

Secondary outcome

The secondary study outcomes are: number of adverse events (adverse events related to ICD shock with consequences and adverse events related to syncopal/near syncopal events); number of appropriate/inappropriate and successful/unsuccessful ATPs/shocks; quality of life and distress (anxiety/depression).

Study description

Background summary

Several studies on primary and secondary prevention of sudden cardiac death have proved the benefit of implantable cardioverter defibrillator (ICD) therapy in prolonging life (1-3). However, retrospective analyses of the mile stone trials for primary prophylactic ICD therapy demonstrated that a reduction in the incidence of sudden cardiac death was counterbalanced by an increased risk in subsequent heart failure death (4). Especially patients who received appropriate ICD therapy for ventricular tachyarrhythmia (VT) were at higher

risk for mortality due to heart failure (5). An ICD shock - whether appropriate or inappropriate - was an independent risk factor for mortality in the SCD-HeFT trial (6). A meta-analysis revealed that "ICD shocked" patients had a poorer survival compared with anti tachycardiac pacing (ATP)-only treated patients (7). Shocks have also been shown to impact adversely on quality of life and symptoms of anxiety and depression (8), although the evidence for an adverse effect of shocks on quality of life and distress is not consistent even in the major primary and secondary prevention trials that included quality of life as a secondary outcome measure (9). Moreover, there is increasing evidence that the psychological status and profile of the ICD patient is an important determinant of both the onset of VT (10,11) but also survival (12-14).

To improve the prognosis and quality of life of ICD patients, a reduction of ICD shocks whether appropriate or inappropriate is necessary. One already known possibility to reduce shocks is programming ATP for fast VT's (15), but in comparison to shock delivery ATP started without delay and an unknown number of non-sustained VT's might be unnecessarily treated by the ICD with the risk of converting the VT into VF. In the shock arm of the PAINFREE II trial 34% of the fast VT's did not need any ICD therapy because of spontaneous termination during capacitor charging. In the non-randomized PREPARE study, it was shown that with the prolonging of the VT/VF detection (30/40) the number of appropriate and inappropriate shocks could be significantly reduced (16). However, also in this trial an unknown number of non-sustained fast VT's were unnecessarily treated because ATP was delivered in less than 10 s. Although SVT/VT discrimination was enabled, 30% of the shocks were caused by SVT's.

An Enhanced ICD programming strategy, as defined below, might further reduce ICD-shocks, improve quality of life, and survival of ICD patients:

Enhanced ICD strategy:
• enhanced VT/SVT discrimination
• prolonged VT/VF detection to support spontaneous termination of VT/pVT
• not to treat hemodynamic stable VT's in which ATP may accelerate the VT into a life-threatening VT or VF

Study objective

Primary objective:
• To investigate whether Enhanced programming is safe for primary and secondary prevention patients

Secondary objectives:
• Investigate the impact of Enhanced programming on adverse events (related to ICD shock with consequences and related to syncopal/near syncopal events)
• Investigate the impact of Enhanced programming on ATPs/shocks (appropriate/inappropriate; successful/unsuccessful).
• Investigate the impact of Enhanced programming on quality of life and

distress (i.e., anxiety/depression)

Study design

The study is set up as a prospective, single-arm safety monitoring study. The device follow-up assessments will take place at 2-, 6- and 12 months post implantation, and every 6 months afterwards until the last included patient has completed the 12 month follow-up. Patients will complete a questionnaire booklet at baseline (1 week - 1 day prior implantation), 3-, 6- and 12-months post-implantation.

Intervention

- Enhanced ICD programming:
VT monitor: > 166/min
fVT: > 182/min; via VF 60/80 intervals (number of intervals to start ATP after approximately 20 s); 3 x ATP (8 stimuli, 88%, scan 20 ms); shock 1-5: 35 J; redetection 30/40 intervals
VF: > 250/min; via VF 60/80 intervals (number of intervals to start therapy after approximately 15 s); 1 x ATP (8 stimuli, 88%) during charging; all shocks: 35 J; redetection 30/40 intervals

SVT/VT discrimination is turned on, high rate time out is *OFF*
SVT/VT discrimination single chamber: stability, wavelet; SVT upper rate limit: 222/min
SVT/VT discrimination dual/triple chamber: P/R logic, wavelet; SVT upper rate limit: 222/min
T-wave oversensing and lead noise discrimination is turned on in all devices

1) In patients with known sustained VT*s the VT zone may be programmed to lower heart rates or ATP/shock therapy may be programmed in the VT zone when hemodynamic instability is expected.

Study burden and risks

We expect that the Enhanced programming strategy will lead to a reduction in ICD therapy with subsequent benefits to the quality of life and well being of patients. However, because of the longer detection duration, patients with an the Enhanced programming face a slightly higher chance of feeling heart palpitations and getting unconscious during fast rhythm disturbances. The risk associated with participation in the study is therefore estimated to be moderate. Since the ENHANCED-ICD trial is a safety study, additional unexpected adverse effects may be possible. However, if there should be a medical indication for a more conventional ICD programming in a subject with an Enhanced programming, the programming will be adapted immediately, to ensure

the safety of the patient.

Contacts

Public
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients implanted with a Medtronic ProtectaTM ICD (VR or DR) or CRT-D, between 18-80 years of age, with a primary or secondary prophylactic indication for ICD therapy according to the current European guidelines, speaking and understanding Dutch, and providing written informed consent will be eligible to participate.

Exclusion criteria

Patients with a life expectancy less than 1 year, with a history of psychiatric illness other than affective/anxiety disorders, on the waiting list for heart transplantation or with insufficient knowledge of the Dutch language will be excluded.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2013
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Implantable Cardioverter Defibrillator (ICD) or Cardiac Resynchronization Therapy Defibrillator (CRT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-03-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-06-2014
Application type:	Amendment
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	NL40047.041.12