ISRCTN82728969 https://doi.org/10.1186/ISRCTN82728969

Dual chamber and atrial tachyarrhythmias adverse events study

Submission date	Recruitment status	[_] Prospectively registered
13/12/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2016	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00157820

Protocol serial number
DATAS

Study information

Scientific Title
Dual chamber and Atrial Tachyarrhythmias Adverse events Study

Acronym
DATAS

Study objectives
To analyse the ability of dual chamber implantable cardioverter defibrillator (DC ICD) (dual chamber [DDED] defibrillator) to reduce clinically significant adverse events compared with single chamber implantable cardioverter defibrillator (SC ICD) in a non-selected population with conventional indications for implantable cardioverter defibrillator (ICD) implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Documented approval of the investigational plan by the Institutional Review Board (IRB) or Ethics Committee (EC) affiliated with the study centre is required for starting the study.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tachyarrythmias, automatic implantable cardioverter defibrilator (ICD)

Interventions
Interventions:
Analyse the ability of DDED to reduce clinically significant adverse events as compared to SC ICD (VVEV) in a non selected population with conventional indication of ICD implantation.

Three arms: two of them (SC simulated and DC true) cross-over, and the third (SC true) parallels the other two. A 1-month wash out period after the cross-over is included to avoid influence of the remodeling associated with pacing mode.

Patients will be followed-up at 1, 4, 8, 9, 13 and 17 months. At enrolment, 8 and 17 months, the quality of life questionnaires, a 6-minute walk test and echo parameters will be recorded, as well as reevaluation of the cardiovascular history.

Intervention Type
Device

Primary outcome(s)
To determine whether use of DDED ICD results in a significant decrease in the number of clinically significant adverse events (CSAE) as follows:
1. All-cause mortality
2. Invasive intervention, hospitalisation (greater than 24 hours) or prolongation of hospitalisation due to cardiovascular cause

3. Inappropriate shocks (two or more episodes with inappropriate shocks)
4. Sustained symptomatic atrial tachyarrhythmias that:
4.1. Require urgent termination, or
4.2. Last more than 48 hours leading to therapeutic intervention

Key secondary outcome(s)
1. Number of each of the components of the CSAE
2. Arrhythmia related:
2.1. Atrial tachyarrhythmia
2.2. Frequency and burden
2.3. Ventricular tachyarrhythmia frequency and burden number of appropriate shocks
2.4. Number of inappropriate shocks
2.5. Need for reprogramming
2.6. Need for medication/radiofrequency ablation (RFA) for arrhythmia control
2.7. Pacemaker syndrome
2.8. Development of dual chamber pacing indication
3. Cardiovascular related:
3.1. New York Heart Association (NYHA) functional class
3.2. Exercise capacity
3.3. Left ventricular ejection fraction (LVEF)
3.4. Reduction of medication (diuretics)
4. Quality of life:
4.1. Evaluated by the 36-item Short Form Health Survey (SF-36)
4.2. Minnesota living test, with heart failure and Symptom Checklist instruments

Completion date
01/04/2005

Eligibility

Key inclusion criteria
Meet Class I implantation criteria for single chamber implantable cardioverter defibrillator according to guidelines

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Permanent atrial fibrillation
2. Non structural heart disease
3. Patient meets implantation criteria for dual-chamber pacing (symptomatic sinus node disease,

all 2nd atrioventricular (AV) block [except asymptomatic Mobitz I] and all 3rd degree AV block)
4. Previous system implanted (ICD or pacemaker)
5. Mechanical right heart valve
6. Medical conditions that would preclude the testing required by the protocol, or limit study participation
7. Unwilling or unable to cooperate or give written informed consent, or the patient is a minor and legal guardians refuse to give informed consent
8. Inaccessible for follow-up at the study centre
9. Biventricular stimulation or re-synchronisation
10. Enrolled or planning to enrol in other clinical trials during the clinical study

Date of first enrolment
01/11/2000

Date of final enrolment
01/04/2005

Locations

Countries of recruitment
United Kingdom

Germany

Israel

Italy

Portugal

Spain

Study participating centre
Av. Tres Cruces s/n
Valencia
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46014

Sponsor information

Organisation
Medtronic Inc. (USA)

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2008		Yes	No
Protocol article	Protocol	01/03/2004		Yes	No
Basic results				No	No