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# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT00157820

**Secondary identifying numbers**
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.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
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

### Secondary outcome measures
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

### Overall study start date
01/11/2000

### 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

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
360

### 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
Germany

Israel

Italy

Portugal

Spain

United Kingdom

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

# Sponsor information

**Organisation**
Medtronic Inc. (USA)

**Sponsor details**
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Minneapolis
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**Sponsor type**
Industry

**Website**
http://www.medtronic.com/

**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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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? |
|---|---|---|---|---|---|
| Basic results | | | | No | No |
| Protocol article | Protocol | 01/03/2004 | | Yes | No |
| Results article | Results | 01/05/2008 | | Yes | No |