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MAVERIC: Midlands trial of amiodarone vs electrophysiology-guided interventions and cardio-defibrillator in ventricular arrhythmias.

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 21/12/2009	**Condition category** 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

Secondary identifying numbers
ID6

Study information

Scientific Title

Acronym
MAVERIC

Study objectives
The optimal way to manage patients who present with sustained ventricular tachycardia (VT), ventricular fibrillation (VF) or sudden cardiac death (SCD), especially in the context of comparing the traditional approach of empirical amiodarone against electrophysiology-guided interventions, which include myocardial revsacularisation, programmed ventricular stimulation and the implantable cardioverter-defibrillator (ICD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Heart disease

Interventions
Electrophysiology + implantable cardioverter defibrillators (ICDs) versus Amiodarone empirically

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Death
2. Arrhythmia recurrence
3. Hospitalisation
4. Drug use
5. Quality of life
6. Cost of managing patients

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/1996

Completion date
30/11/1999

Eligibility

Key inclusion criteria
1. Patients who presented with sustained ventricular tachycardia (VT), ventricular fibrillation (VF) or sudden cardiac death (SCD) and survived to reach hospital within the Midlands from Feb 1997 to Jan 1999 were actively identified and entered into the study.
2. Patients who were not of child-bearing age or had a life-expectancy of <6 months from a non-arrhythmic cause were approached for entry into the trial.

Patients who were ineligible for or refused to join the trial were entered into the study's registry.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
214 (Added 19/11/09)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/11/1996

Date of final enrolment
30/11/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Cardiology
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Cardiovascular Disease and Stroke National Research and Development Programme (UK)

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?
Protocol article	protocol	01/07/1998		Yes	No
Results article	results	01/07/2004		Yes	No