

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/12/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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 revascularisation, 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