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Substrate Mapping and Ablation in Sinus rhythm to Halt Ventricular Tachycardia

Submission date	Recruitment status	[_] Prospectively registered
19/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2008	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
SMASH VT

Study objectives
This study examines the hypothesis that prophylactic catheter ablation, that is ablation before Implantable Cardioverter Defibrillator (ICD) shocks, can safely decrease the possibility of subsequent ICD therapy in post-Myocardial Infarction (MI) patients receiving a defibrillator after surviving a life-threatening ventricular arrhythmic event.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Partners Institutional Review Board (protocol: 2000p-000884).

Study design
Randomised, non-blinded, controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ventricular tachycardia

Interventions
Randomisation between:
1. Implantable defibrillator
2. Implantable defibrillator plus catheter ablation of ventricular tachycardia

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Defibrillator events (shocks and anti-tachycardia therapy)

Secondary outcome measures
1. Mortality
2. ICD shocks
3. Left ventricular ejection fraction
4. Heart failure status

Overall study start date
01/08/2000

Completion date
01/10/2003

Eligibility

Key inclusion criteria
Men and women who were at least 18 years old were eligible for the study if they had a history of an MI as documented by an electrocardiogram or cardiac imaging and had a planned or recent (within six months) implantation of an ICD for either:
1. Ventricular Fibrillation (VF) arrest
2. Hemodynamically-unstable Ventricular Tachycardia (VT)
3. Syncope and inducible VT during invasive electrophysiologic testing (for this group, syncope is assumed to be the qualifying spontaneous arrhythmic event)
4. Patients who had received an ICD for primary prophylaxis and then experienced a single appropriate ICD therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
128

Key exclusion criteria
1. Treated with a Class I/III antiarrhythmic drug
2. The substrate for the ventricular arrhythmia was thought not to be due to the myocardial infarction
3. Active ongoing cardiac ischemia was felt to be the cause of the ventricular arrhythmia;
4. Incessant or multiple VT episodes necessitating some form of treatment drugs or ablation
5. Unable to give informed consent

6. If the patient had experienced a stroke within 30 days
7. Contraindication to anticoagulation
8. Any medical/non-medical condition likely to prevent completion of the trial

Date of first enrolment
01/08/2000

Date of final enrolment
01/10/2003

Locations

Countries of recruitment
Czech Republic

United States of America

Study participating centre
Chief, Cardiovascular Division
Boston, Massachusetts
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02215

Sponsor information

Organisation
Beth Israel - Deaconess Hospital (USA)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04drvxt59

Funder(s)

Funder type
Other

Funder Name
Investigator funded and initiated trial

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?
Results article	Results:	27/12/2007		Yes	No