

Substrate Mapping and Ablation in Sinus rhythm to Halt Ventricular Tachycardia

Submission date 19/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/08/2008	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

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

Study type(s)

Treatment

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(s)

Defibrillator events (shocks and anti-tachycardia therapy)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
United States of America
02215

Sponsor information

Organisation
Beth Israel - Deaconess Hospital (USA)

ROR
<https://ror.org/04drvxt59>

Funder(s)

Funder type
Other

Funder Name
Investigator funded and initiated trial

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:	27/12/2007		Yes	No