# Substrate Mapping and Ablation in Sinus rhythm to Halt Ventricular Tachycardia

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/09/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/09/2006	Completed	[X] Results
<b>Last Edited</b> 06/08/2008	Condition category Circulatory System	[] Individual participant data
00/00/2000	Circulatory System	

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** 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

### 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

Αll

#### 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

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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleResults:27/12/2007YesNo