

# Applications of body surface mapping in cardiac resynchronisation therapy and ventricular tachycardia

<b>Submission date</b> 03/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/07/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2007	<b>Condition category</b> 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**  
RGHT000233

# Study information

## Scientific Title

### Study objectives

1. Electrocardiographic Imaging (ECGI) using potentials derived from the body surface can be used to identify electrical dyssynchrony within the Left Ventricle (LV), along with activation patterns and regions of slow conduction. It could therefore be used to predict response to cardiac resynchronisation therapy, and ultimately to guide placement of the LV pacing lead to the optimal site.
2. ECGI using body surface potentials acquired noninvasively is of comparable accuracy to endocardial data acquired invasively in determining sites of pacing of the LV endocardium and patterns of activation.
3. ECGI is comparable to endocardial data acquired invasively in locating the origin of Ventricular Tachycardia (VT) substrates and may provide useful information over and above endocardial data to aid radiofrequency ablation of this tachyarrhythmia.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The Office for Research Ethics Committees in Northern Ireland (ORECNI), approved on 16/09/2005 (ref: 05/NIR01/139)

### Study design

Non randomised controlled trial.

### Primary study design

Interventional

### Secondary study design

Non randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Diagnostic

### Participant information sheet

### Health condition(s) or problem(s) studied

Left ventricular dysfunction

### Interventions

#### 1. CRT study

This is a pilot study during which 50 consecutive patients undergoing CRT implantation will be identified and worked up appropriately (there is no control group in this study and all participants will be given the same interventions). All participants will undergo baseline

assessment to include echocardiography, 6 minute walk testing, cardiopulmonary stress testing, quality of life assessment (questionnaire) and N-terminal Pro-BNP measurement. Body Surface Mapping (BSM) will be performed at baseline and the day following device implantation during different pacing modalities. They will then be followed up with a single visit at 6 months, at which time all of these tests will be repeated.

## 2. ECGI validation study:

A qualitative study comparing ECGI with data acquired invasively using noncontact endocardial mapping as gold standard. 10 patients undergoing invasive ElectroPhysiological Studies (EPS) requiring access to the left ventricle will be recruited. All patients will have an ECHO at baseline and undergo simultaneous body surface mapping and invasive endocardial mapping during multi-site pacing of the LV endocardium. BSM utilises a plastic 80-electrode mapping harness applied to the anterior and posterior torso. Noncontact endocardial mapping uses the previously validated EnSite 3000 system. This study will enable a qualitative comparison of both imaging modalities for localisation of pacing sites as well as activation sequences. There will be no follow-up for the patients in this sub-study.

## 3. VT study:

10 patients requiring VT ablation or simply EPS for induction of ventricular arrhythmias will be studied using both invasive and noninvasive modalities. This is a purely qualitative study.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome measure**

CRT study:

Response to CRT (assessed clinically using echo, 6 minute walk distance, cardiopulmonary stress testing, and functionally using quality of life questionnaire and NYHA symptom class). This can be assessed in conjunction with pacing site localisation using ECGI in relation to regions of slow conduction/scar tissue.

ECGI validation and VT studies: These are qualitative studies whereby ECGI data and data acquired invasively are compared directly. Therefore there is no discrete end-point.

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

01/10/2005

### **Completion date**

31/07/2007

## **Eligibility**

### **Key inclusion criteria**

Cardiac Resynchronization Therapy (CRT) study:

1. Poor LV function with ejection fraction on echocardiogram (ECHO) <35%

2. Symptomatic with New York Heart Association (NYHA) class 2-4
  3. Dilated LV (>55 mm)
  4. Any QRS duration (representing the duration of ventricular depolarisation)
- LV dysfunction can be of any aetiology. All patients must be able and willing to give written informed consent.

**ECGI validation study:**

Patients must require EPS/ablation of tachyarrhythmias requiring LV access e.g. VT ablation/EPS, Brugada EPS, left sided pathways. All must be willing and able to give written informed consent.

**VT study:**

All patients must require EPS for induction of LV tachyarrhythmias or ablation of VT. Again all must give written informed consent.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

70 (CRT study, 50; ECGI validation study, 10; VT study, 10)

**Key exclusion criteria**

**CRT study:**

1. Ejection fraction on ECHO >35%
2. Unable or unwilling to come back for 6 month follow-up
3. Unable or unwilling to give written informed consent

**ECGI validation and VT studies:**

1. Procedures not requiring access to the LV
2. Bleeding conditions
3. Clotting disorders
4. Unwilling to give written informed consent
5. Age <18 years

**Date of first enrolment**

01/10/2005

**Date of final enrolment**

31/07/2007

## **Locations**

**Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**  
**Regional Medical Cardiology Centre**  
Belfast  
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## **Sponsor information**

### **Organisation**

Royal Victoria Hospital (UK)

### **Sponsor details**

c/o Professor Ian Young  
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### **Sponsor type**

Hospital/treatment centre

### **ROR**

<https://ror.org/03rq50d77>

## **Funder(s)**

### **Funder type**

Not defined

### **Funder Name**

Frances and Augustus Newman Foundation (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?
<a href="#">Results article</a>	results	01/11/2007		Yes	No