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

Submission date 03/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/07/2007	**Overall study status** Completed	
Last Edited 02/10/2007	**Condition category** Circulatory System	

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 intervenions). 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 muti-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 writted 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
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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?
Results article	results	01/11/2007		Yes	No