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Optimisation of defibrillation for ventricular fibrillation: the use of low tilt waveforms for the defibrillation of ventricular fibrillation

Submission date 01/05/2007	**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 09/07/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jennifer Adgey

Contact details
Regional Medical Cardiology Centre
Royal Hospitals
Grosvenor Road
Belfast
United Kingdom
BT12 6BA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RGHT000386

Study information

Scientific Title

Study objectives
Overall survival rates from Ventricular Fibrillation (VF) are currently very poor. A more efficient biphasic defibrillator with novel low-tilt technology could improve the chances of terminating VF early thus increasing the chances of survival. The primary aim of this study is to determine whether the use of a defibrillator with a low-tilt biphasic waveform will improve the success of defibrillation of ventricular fibrillation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This project has been reviewed and approved by the Office for Research Ethics Committees in Northern Ireland (ORECNI) on the 8th November 2006 (ref: 06/NIR02/108).

Study design
Randomised, controlled, safety and feasability study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Ventricular fibrillation/cardiac arrest

Interventions
This will be a safety and feasibility study which aims to show equivalence in the removal of ventricular fibrillation during cardiac arrests between a novel low-tilt defibrillating device and the standard-tilted defibrillator currently in use in the trust (Philips Agilent Heartstart XL).

Standard-tilted biphasic defibrillators are currently available on all hospital wards, to the cardiac arrest team and the physician-led cardiac ambulance. Randomisation will occur on a daily basis between the novel low-tilt device and the standard-tilted defibrillator. The randomised device will be made available to the cardiac arrest team, in the coronary care unit and also to the physician-led cardiac ambulance.

It will not be possible to blind those staff delivering the defibrillating shocks to the device in use due to their appearances.

Patients found to be in VF will receive treatment according to the resuscitation guidelines issued by the Resuscitation Council (UK) 2005. The standard-tilted device will deliver shocks at 150 J and the low-tilt device 120 J. Following any three unsuccessful shocks, a rescue shock of 200 J will be used from the standard-tilted defibrillator.

All shocks will be delivered via standard self-adhesive pads which have previously been validated for clinical use. Defibrillating shocks will be delivered by a doctor, nurse or resuscitation officer who is fully trained in advanced life support.

The following non-invasive parameters will also be recorded and analysed:
1. Time from collapse to arrival of emergency services
2. Time to first shock
3. Whether Cardio-Pulmonary Resuscitation (CPR) is performed pre-shock
4. Any delays in shock delivery
5. Duration of arrest
6. Drugs administered
7. Patient demographics
7. Aetiology of VF (where possible)

There will be no follow up of any patients. Patients will only be included in the study at the time of required defibrillation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary endpoint of the study will be termination of ventricular arrhythmia for greater than or equal to five seconds following shock delivery. This will be determined by analysis of the defibrillator Electrocardiogram (ECG) tracing post-cardiac arrest.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2006

Completion date
30/11/2007

Eligibility

Key inclusion criteria
All adult patients in cardiac arrest with ventricular fibrillation as the identified rhythm.

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
110

Key exclusion criteria
Patients with existing 'Do not resuscitate' orders.

Date of first enrolment
01/12/2006

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Regional Medical Cardiology Centre
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Royal Hospitals Trust (UK)

Sponsor details
Royal Research Office
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/03rq50d77

Funder(s)

Funder type
Charity

Funder Name
The Heart Trust Fund (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		01/11/2007		Yes	No
Results article	results	01/12/2012		Yes	No