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Non-invasive, bedside assessment of systemic endothelial function: a predictor of mortality in intensive care?

Submission date 19/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/06/2009	**Overall study status** Completed	
Last Edited 29/01/2013	**Condition category** Haematological Disorders	

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
RGHT000413

Study information

Scientific Title
Function of the Endothelium in Critical Care: a prospective observational cohort study

Acronym
FECC

Study objectives
Bedside assessment of systemic endothelial function using non-invasive pulse wave analysis (PWA) predicts outcome in intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northern Ireland HPSS REC 3 approved on the 21st June 2007 (ref: 07/NIR03/30)

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Systemic endothelial function in critical care

Interventions
Recruited patients will be categorised as follows:
1. Medical
2. Surgical
3. Trauma
4. Burns

Baseline information to be recorded will include:
1. Patient demographics
2. Physiological data

3. Plasma biochemistry profile (including liver function)
4. Full blood picture and coagulation screen
5. Acute Physiology and Chronic Health Evaluation II (APACHE II) score
6. Simplified Acute Physiology Score II (SAPS II) score
7. Sequential Organ Failure Assessment (SOFA) score

All clinical data and measurements will be undertaken and recorded by the research fellow. Systemic endothelial function as measured by pulse wave analysis will be performed non-invasively using the SphygmoCor™ pulse wave analysis system (AtCor Medical Pty Ltd, Australia). In addition the following surrogate markers of endothelial function will be recorded:
1. Albumin creatinine ratio (ACR)
2. Plasma von Willebrand Factor (vWF)
3. Plasma adhesion molecules, ICAM, VCAM and E-selectin

Blood and urine samples will be taken at admission. Urinary albumin and creatinine concentrations will be measured by ELISA and colorimetric assays, respectively. Von Willebrand Factor and adhesion molecules, ICAM, VCAM, E-Selectin will be measured using an ELISA. A blood sample will be taken 20 minutes after administration of the nebulised salbutamol. This sample will be analysed for a plasma salbutamol concentration, again using ELISA. In this way systemic uptake of salbutamol will be confirmed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Intensive Care Unit (ICU) mortality

Secondary outcome measures
1. Length of ICU stay
2. Number of ventilator days
3. Incidence of organ failures
4. Need for continuous renal replacement therapy
5. Duration of inotropic support

Overall study start date
01/07/2007

Completion date
01/12/2009

Eligibility

Key inclusion criteria
All adult patients admitted to the regional intensive care unit at the Royal Group of Hospitals, Belfast will be eligible for inclusion in the study.

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
182

Key exclusion criteria
1. Aged less than 18 years old
2. Pregnancy
3. Inability to achieve radial arterial access
4. Known allergy or sensitivity to salbutamol or glyceryl trinitrate (GTN)
5. Patients transferred from other intensive care units
6. Patients unlikely to survive more than 24 hours
7. Patients with an advance directive regarding limitation of treatment
8. Patients who have a "Do Not Attempt Resuscitation" (DNAR) order in place
9. Lack of consent

Date of first enrolment
01/07/2007

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Regional Intensive Care Unit
Belfast
United Kingdom
BT12 6BA

Sponsor information

Organisation
Royal Victoria Hospital (UK)

Sponsor details
Grosvenor Road
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United Kingdom
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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03rq50d77

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Anaesthetists/British Journal of Anaesthesia (UK) - Grant (2008)

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	01/04/2011		Yes	No