

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	<input type="checkbox"/> Prospectively registered
Registration date 05/06/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/01/2013	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Screening

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(s)

Intensive Care Unit (ICU) mortality

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Northern Ireland

Study participating centre**Regional Intensive Care Unit**

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Royal Victoria Hospital (UK)

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

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