

# 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

**Registration date**  
05/06/2009

**Overall study status**  
Completed

**Last Edited**  
29/01/2013

**Condition category**  
Haematological Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Brian Mullan

### Contact details

Regional Intensive Care Unit  
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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  
Belfast  
Northern Ireland  
United Kingdom  
BT12 6BA  
+44(0)28 9024 0503  
mary.williams@belfasttrust.hscni.net

**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?
<a href="#">Results article</a>	results	01/04/2011		Yes	No