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# Cortisol Profiles in the Critically Ill

**Submission date**
24/11/2017

**Recruitment status**
No longer recruiting

**Registration date**
11/12/2017

**Overall study status**
Completed

**Last Edited**
24/02/2020

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cortisol is a steroid that the body produces naturally. It is normally produced in a 'diurnal rhythm'. This means that its levels change throughout the day. When people are healthy, there are high levels in the morning and low levels at about 4pm (this is why you feel awake in the morning and sleepy in the late afternoon). Pulses coming from your brain generate this rhythm; there are lots of big pulses in the morning and fewer, smaller pulses in the late afternoon. It is not known what happens to these pulses when people are unwell after heart surgery. However, we think it is important to know what happens to these pulses because steroids help protect the body from large stressors (of which heart surgery is one). We think that people who do not produce enough steroid when they are on the intensive care unit do not do as well (they stay on the intensive care unit longer and need more medicines to help keep their blood pressure up). On the other hand, too much steroid causes its own side effects such as poor wound healing and short-term diabetes. The aim of this study measures what actually happens to patients' pulses of cortisol. This may help clinicians to work out who needs extra, or if we are giving more than we need to. It has been shown that these pulses change dramatically when a patient is chronically unwell and early results from current work we are doing shows large derangements in those having routine cardiac surgery. This study is designed to see what happens to these pulses when people are critically ill. Once we know what is 'normal' during critical illness, we can begin to give steroids to patients in a more tailored way.

Who can participate?
Males aged 18 to 80 who are undergoing cardiac surgery.

What does the study involve?
Patients who took part in the study had small blood samples (0.7 – 2mls) every ten minutes for 24 hours from the tubes that are already in place. There are no extra needles and the total volume of blood we take is less than a tea-cup.

What are the possible benefits and risks of participating?
There were no direct benefits to those taking part. There was also little risk taking part as only small blood samples were being taken.

Where is the study run from?
Bristol Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
March 2012- March 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Mr Jonathan Evans

# Contact information

### Type(s)
Public

### Contact name
Mr Jonathan Evans

### Contact details
Clinical Trials Evaluation Unit
Level 7, Queens Building
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Bristol
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# Additional identifiers

### Integrated Research Application System (IRAS)
91553

### Protocol serial number
7.0, IRAS 91553

# Study information

### Scientific Title
Cortisol profiles in the critically ill after cardiac surgery

### Acronym
Cortisol 2

### Study objectives
The aim of this study is to investigate what happens to cortisol pulses when people are critically ill. Once we know what is ‘normal’ during critical illness, we can begin to give steroids to patients in a more tailored way.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Frenchay Research Ethics Committee, 10/08/2012, ref: 12/SW/0186

### Study design
Observational cross sectional study

### Primary study design
Observational

### Study type(s)
Quality of life

### Health condition(s) or problem(s) studied
Critically ill patients following cardiac surgery

### Interventions
Participants undergo blood sampling for 24 hours via their in situ lines from 8am in the morning. Cortisol sampling of 0.7ml is taken every 10 minutes. Blood sampling for ACTH occurs at hourly intervals (1ml for each ACTH sample). CBG sampling occus at time points 0 and 24hrs (2ml). Inflammatory mediator sampling (1ml) occurs at four hourly intervals. Total blood volume sampled does not exceed 150mls.

### Intervention Type
Other

### Primary outcome(s)
Cortisol is measured using blood samples taken every ten minutes which will generate a profile over 24 hours.

### Key secondary outcome(s))
1. Adreno-corticotrophic hormone is measured using blood samples taken at hourly intervals
2. Cortisol Binding Globulin (CBG) is measured using blood samples taken at baseline and 24 hours
3. Inflammatory mediators are measured using blood samples taken at every four hours

### Completion date
30/03/2018

## Eligibility

### Key inclusion criteria
1. Consultee of opinion that patient would consent
2. Male
3. Ages 18 – 80 undergoing cardiac surgery
4. At least 2 of the following on day 2 or later post cardiac surgery:
4.1. Ventilation
4.2. Concurrent use of inotropes and/or vasopressors
4.3. Haemo(dia)filtration

### Participant type(s)

Other

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Male

### Total final enrolment
20

### Key exclusion criteria
1. Consultee of opinion that patient would not consent
2. Current or recent (within 3 months) use of glucocorticoids
3. Disorders of the HPA axis
4. Thyroid disease
5. Etomidate use at any stage of the surgical pathway

### Date of first enrolment
20/04/2015

### Date of final enrolment
23/02/2017

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Bristol Royal Infirmary**
University Hospitals Bristol NHS Foundation Trust
Upper Maudlin St
Bristol
United Kingdom
BS2 8HW

## Sponsor information

**Organisation**
University of Bristol

**ROR**
https://ror.org/0524sp257

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation

**Alternative Name(s)**
The British Heart Foundation, the_bhf, BHF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
Once analysed, anonymised datasets generated during the current study can be available on request, please contact bristol-cteu@bristol.ac.uk.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2020 | 24/02/2020 | Yes | No |