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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
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Additional identifiers

EudraCT/CTIS number

IRAS number
91553

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
The patient information sheet can be made available on request (email: jonathan.evans@bristol.ac.uk)

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 measure
Cortisol is measured using blood samples taken every ten minutes which will generate a profile over 24 hours.

Secondary outcome measures
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

Overall study start date
21/03/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
20

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
England

United Kingdom

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

Sponsor details
RED
3rd Floor
Senate House
Tyndall Ave
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

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

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. The protocol can be made available on request (email: jonathan.evans@bristol.ac.uk).

Intention to publish date
30/04/2018

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