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Peacock - a paediatric cortisol study

Submission date
30/11/2017

Recruitment status
No longer recruiting

Registration date
18/12/2017

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Circulatory System

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is aimed at understanding how a child's body responds to cardiac (heart) surgery compared to those undergoing cardiac investigations. It is known from adults that when someone has cardiac surgery it puts stress on the body. The stress response is the way the body responds to surgery in order to re-establish its equilibrium. Being able to understand and control this response may influence outcomes of children having heart surgery. The stress response has never been studied in detail in children of various ages. There are several stress hormones in the body, but the most important one is called cortisol. In this study cortisol and other hormones are measured at the time of surgery to understand this process. To do this, very frequent measurements are needed. In addition to taking a few blood measurements other new techniques are used to measure cortisol levels in the tissue.

Who can participate?
Patients aged 0-5 or 10-16 undergoing cardiac surgery or cardiac investigations

What does the study involve?
Participants' levels of cortisol and other hormones are measured using blood samples and other new techniques at multiple timepoints over 24 hours.

What are the possible benefits and risks of participating?
By understanding children's stress response researchers may be able to design treatments to improve recovery in children undergoing heart surgery or other heart procedures. There are no direct benefits to participants. The only potential risk is infection at the site of the catheter (tube) insertion. This risk should be very low and every possible measure will be made to prevent this.

Where is the study run from?
University Hospital Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2015 to December 2022

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

Who is the main contact?
Mr Jonathan Evans

Study website
https://bristoltrialscentre.blogs.bristol.ac.uk/details-of-studies/peacock/

Contact information

Type(s)
Public

Contact name
Mr Jonathan Evans

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4.0

Study information

Scientific Title
Hypothalamic-pituitary-adrenal (HPA) axis: function and control mechanisms in children undergoing cardiac surgery

Study objectives
The pattern of cortisol secretion varies qualitatively and quantitatively in various paediatric age groups undergoing corrective heart surgery. There are differences in the secretory patterns in neonates and infants with cyanotic vs. acyanotic congenital heart disease, pubertal vs. post-pubertal periods and patients having heart surgery on cardiopulmonary bypass vs cardiac catheter procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Central Bristol Research Ethics Committee, 20/09/2016, ref: 16/SW/0186

Study design
Single-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Paediatric patient undergoing cardiac surgery and other cardiac investigations

Interventions
Current interventions as of 11/08/2020:
This is a two-centre descriptive study of the ultradian rhythms of cortisol that occur in neonates, infants and children. Thirty-six patients undergoing cardiac surgery will have 24-hour cortisol microdialysis and serum cortisol ACTH, CBG, IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha measured at six timepoints for neonates (post-CPB excluded) and seven timepoints for infants and older children. CBG will be measured at four timepoints. To minimise patient distress, the trialists will synchronise a preoperative, basal, sample in the preoperative assessment clinic and before anaesthesia induction, along with other routine preoperative blood samples. Intraoperatively,

samples will be collected from the arterial or central line, pre-CPB and post CPB. Postoperatively, blood samples will be spaced at 6, 12 and 24 hours postoperatively.

The cohort will be further split into 4 groups. Neonates (6 cyanotic heart disease), Infants (6 cyanotic and 6 acyanotic heart disease), 6 children aged 1-5 and, 12 patients aged 10-16. For the 10-16 years age group the trialists will recruit only the patients operated on in the morning. This group will be further split into two subgroups - males and females (6 per group). Pubertal status of the 10-16 group will be recorded based on clinical criteria (e.g. presence of breast buds, periods, in girls and a testis volume greater than 4 ml in boys). In addition, patients in the 10-16 group will have one morning sample of FSH, LH, oestradiol or testosterone. The trialists will also recruit 24 patients undergoing cardiac investigation. This is sub-divided into: 6 infants and 6 children aged 1-5-years-old, and 12 patients aged 10-16. The age 10-16 group will comprise of 6 males and 6 female patients. The cardiac investigation cohort patients will have basal pre-op sample via the cannula inserted for anaesthesia and microdialysis sampling for 24 hours.

Infants, and children aged 10-16: At each time point the trialists will measure serum cortisol, ACTH and interleukins. CBG will be measured at three timepoints over 24 hours (induction, 6 hours and 24 hours only). This results in a total blood volume of 1.3 ml per draw for time points including CBG sampling and 1.0 ml for time points without CBG. Measuring at six timepoints within 24 hours (e.g. excluding the pre-assessment clinic sample) results in a cumulative, perioperative blood volume draw of 6.9ml. Previous policies and recommendations reported the safe limits of blood sampling for research in healthy children and the proposed study is well within the limits. Most guidelines quote a maximum cumulative draw volume ranging from 5-10 % of the total circulating volume, 50 ml total over 8 weeks (whichever is less) and the lowest volume quoted is of 3 ml/kg in critically ill children.

Neonates: Neonates with cardiac disease are by their nature smaller than children without cardiac disease and therefore constitute a special case. Hazinski et al 48 reported the circulating volumes at various ages from which the trialists can calculate the circulating volume depending on weight, and calculate the maximum 5 % cumulative blood volume. For example, the circulating volume of a 2 kg neonate is 180 ml (90 ml kg x 2) and 5 % of this volume is 9 ml. However, to be within all guidelines, the trialists will use the 3 ml/kg limit. This would result 3 x 2 = 6 ml maximum blood volume for measurements. This means that they would have to limit the weight in neonates to 2 kg and reduce the number of sampling time-points within the 24-hour period from 6 to 5. In this case, they will omit the post CPB sample (see Figure 7) in order to be within the safety limits of all guidelines. This results in a cumulative blood volume for 24 hours of 5.9 mL which is below the 6 ml lowest limit of the guideline.

For the cardiac investigation cohort, blood sampling for serum cortisol, ACTH, CBG and IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha will take place at only one timepoint pre-operatively. For this group the weight limit can be lowered because of need for only one sample (1.3 ml total draw). Therefore, blood sampling will be theoretically possible in the cardiac cohort in neonates with a weight above 0.33 kg (although few, if any babies are likely to be as small as this).

Modified ultrafiltration with cardiopulmonary bypass is commonly used in paediatric cardiac surgery to haemoconcentrate patients but also in an attempt to reduce the systemic inflammatory response to CPB. Several studies demonstrated a decrease in the levels of certain pro-inflammatory cytokines such as IL-6, IL-8 or TNFα 49. Although this could alter the levels of IL-6 that will be measured in the blood the trialists believe that the free cortisol measured by subcutaneous microdialysis will not be affected because of the lipophilic nature of its molecule and large volume of distribution.

It is common for paediatric surgery patients to receive blood products such as red blood cell packs, fresh frozen plasma or cryoprecipitate perioperatively. The trialists will also assay cortisol and ACTH in 10 units each of fresh frozen plasma or cryoprecipitate, to determine the level of hormones in these blood products and any impact it may have on analyses. They will not test red blood cells as it will not be present in significant amounts after the manufacturing process of this product.

All patients will undergo subcutaneous microdialysis coupled with an automated sampling device. Microdialysis catheters will be inserted in the subcutaneous tissue under aseptic technique in the lateral abdominal wall, below the umbilicus. The procedure will be performed in the anaesthetic/operating room, after anaesthesia. Free cortisol will be measured for 24 hours in total by attaching an automated sampling device.

Previous interventions from 08/10/2019 to 11/08/2020:
This is a single-centre descriptive study of the ultradian rhythms of cortisol that occur in neonates, infants and children. Forty-two patients undergoing cardiac surgery will have 24-hour cortisol microdialysis and serum cortisol ACTH, CBG, IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha measured at 6 time-points for neonates (post-CPB excluded) and 7 time points for infants and older children. CBG will be measured at 4 time points. To minimise patient distress, the trialists will synchronise a preoperative, basal, sample in the preoperative assessment clinic and before anaesthesia induction, along with other routine preoperative blood samples. Intraoperatively, samples will be collected from the arterial or central line, pre CPB and post CPB. Postoperatively, blood samples will be spaced at 6, 12 and 24 hours postoperatively.

The cohort will be further split into 4 groups. Neonates (6 cyanotic heart disease), Infants (6 cyanotic and 6 acyanotic heart disease), 6 children aged 1-5 and, 18 patients aged 10-16. For the 10-16 years age group the trialists will recruit only the patients operated on in the morning. This group will be further split into three subgroups. The pre-pubertal group (6 children) and the post-pubertal groups: 6 males and 6 females. Patients will be allocated to either pubertal or post-pubertal group based on clinical criteria (e.g. presence of breast buds, periods, in girls and a testis volume greater than 4 mL in boys). In addition, the pre- and post-pubertal groups (18 patients) will have one morning sample of FSH, LH, oestradiol or testosterone. The trialists will also recruit a cardiac investigation cohort: 6 infants and 1-5-year-old children. For the age 10-16 group, they will recruit 6 patients for the pre-pubertal group and 12 patients for the post-pubertal group (e.g. 6 males and 6 females). The cardiac investigation cohort patients will have basal pre-op sample via the cannula inserted for anaesthesia and microdialysis sampling for 24 hours.

Infants, pre- and post pubertal children: At each time point the trialists will measure serum cortisol, ACTH and interleukins. CBG will be measured at 3 time points over 24 hours (induction, 6 hours and 24 hours only). This results in a total blood volume of 1.3mL per draw for time points including CBG sampling and 1.0ml for time points without CBG. Measuring at 6 timepoints within 24 hours (e.g. excluding the pre-assessment clinic sample) results in a cumulative, perioperative blood volume draw of 6.9mL. Previous policies and recommendations reported the safe limits of blood sampling for research in healthy children and the proposed study is well within the limits47. Most guidelines quote a maximum cumulative draw volume ranging from 5-10 % of the total circulating volume, 50 mL total over 8 weeks (whichever is less) and the lowest volume quoted is of 3mL/kg in critically ill children.

Neonates: Neonates with cardiac disease are by their nature smaller than children without cardiac disease and therefore constitute a special case. Hazinski et al 48 reported the circulating volumes at various ages from which the trialists can calculate the circulating volume depending

on weight, and calculate the maximum 5 % cumulative blood volume. For example, the circulating volume of a 2 kg neonate is 180 mL (90mL kg x 2) and 5 % of this volume is 9 mL. However, to be within all guidelines, the trialists will use the the 3mLs/kg limit. This would result 3 x 2=6 mL maximum blood volume for measurements. This means that they would have to limit the weight in neonates to 2 kg and reduce the number of sampling time-points within the 24-hour period from 6 to 5. In this case, they will omit the post CPB sample (see Figure 7) in order to be within the safety limits of all guidelines. This results in a cumulative blood volume for 24 hours of 5.9 mL which is below the 6 mL lowest limit of the guideline.

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It is common for paediatric surgery patients to receive blood products such as red blood cell packs, fresh frozen plasma or cryoprecipitate perioperatively. The trialists will also assay cortisol and ACTH in 10 units each of fresh frozen plasma or cryoprecipitate, to determine the level of hormones in these blood products and any impact it may have on analyses. They will not test red blood cells as it will not be present in significant amounts after the manufacturing process of this product.

All patients will undergo subcutaneous microdialysis coupled with an automated sampling device. Microdialysis catheters will be inserted in the subcutaneous tissue under aseptic technique in the lateral abdominal wall, below the umbilicus. The procedure will be performed in the anaesthetic/operating room, after anaesthesia. Free cortisol will be measured for 24 hours in total by attaching an automated sampling device.

Original interventions:
This is a single-centre descriptive study of the ultradian rhythms of cortisol that occur in neonates, infants and children. Forty-eight patients undergoing cardiac surgery will have 24-hour cortisol microdialysis and serum cortisol ACTH, CBG, IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha measured at 6 time-points for neonates (post-CPB excluded) and 7 time points for infants and older children. CBG will be measured at 4 time points. To minimise patient distress, the trialists will synchronise a preoperative, basal, sample in the preoperative assessment clinic and before anaesthesia induction, along with other routine preoperative blood samples. Intraoperatively, samples will be collected from the arterial or central line, pre CPB and post CPB. Postoperatively, blood samples will be spaced at 6, 12 and 24 hours postoperatively.

The cohort will be further split into 4 groups. Neonates (6 cyanotic and 6 acyanotic heart disease), Infants (6 cyanotic and 6 acyanotic heart disease), 6 children aged 1-5 and, 18 patients aged 10-16. For the 10-16 years age group the trialists will recruit only the patients operated on in the morning. This group will be further split into three subgroups. The pre-pubertal group (6 children) and the post-pubertal groups: 6 males and 6 females. Patients will be allocated to

either pubertal or post-pubertal group based on clinical criteria (e.g. presence of breast buds, periods, in girls and a testis volume greater than 4 mL in boys). In addition, the pre- and post-pubertal groups (18 patients) will have one morning sample of FSH, LH, oestradiol or testosterone. The trialists will also recruit a cardiac investigation cohort: 6 infants and 1-5-year-old children. For the age 10-16 group, they will recruit 6 patients for the pre-pubertal group and 12 patients for the post-pubertal group (e.g. 6 males and 6 females). The cardiac investigation cohort patients will have basal pre-op sample via the cannula inserted for anaesthesia and microdialysis sampling for 24 hours.

Infants, pre- and post pubertal children: At each time point the trialists will measure serum cortisol, ACTH and interleukins. CBG will be measured at 3 time points over 24 hours (induction, 6 hours and 24 hours only). This results in a total blood volume of 1.3mL per draw for time points including CBG sampling and 1.0ml for time points without CBG. Measuring at 6 timepoints within 24 hours (e.g. excluding the pre-assessment clinic sample) results in a cumulative, perioperative blood volume draw of 6.9mL. Previous policies and recommendations reported the safe limits of blood sampling for research in healthy children and the proposed study is well within the limits47. Most guidelines quote a maximum cumulative draw volume ranging from 5-10 % of the total circulating volume, 50 mL total over 8 weeks (whichever is less) and the lowest volume quoted is of 3mL/kg in critically ill children.

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All patients will undergo subcutaneous microdialysis coupled with an automated sampling device. Microdialysis catheters will be inserted in the subcutaneous tissue under aseptic technique in the lateral abdominal wall, below the umbilicus. The procedure will be performed in the anaesthetic/operating room, after anaesthesia. Free cortisol will be measured for 24 hours in total by attaching an automated sampling device.

Intervention Type
Other

Primary outcome measure
1. The cortisol profile during the 24-hour measurement period for both cohorts. Tissue cortisol levels are measured using subcutaneous microdialysis in all subjects:
2. For the surgical cohort, total serum cortisol will also be measured at 7 timepoints (pre-op assessment, pre-operative – before anaesthesia induction, pre CPB, post CPB, at 6, 12 and 24 hours postop) for infants and pre- and post pubertal children and at 6 time points for neonates (post-CPB sample excluded). These will be correlated with tissue cortisol levels obtained by microdialysis over 24 hours
3. For the cardiac investigation cohort serum cortisol will be measured pre procedure (e.g 1 time point) for all age groups
4. Pulsatility and interaction of cortisol and ACTH as assessed using a bespoke algorithm

Secondary outcome measures
For the surgical cohort:
1. Adreno-corticotrophic hormone (ACTH), measured by taking blood samples at 7 timepoints (pre-op assessment, pre-operative, pre CPB, post CPB, at 6, 12 and 24 hours postop) for infants and pre- and post pubertal children and at 6 time points for neonates (post-CPB sample excluded)
2. Cortisol Binding Globulin (CBG), measured by taking blood samples at 4 timepoints (pre-op assessment, induction , at 6, and 24 hours postop) for all age groups
3. IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha, measured by taking blood samples at 7 timepoints (pre-op assessment, pre-operative, pre CPB, post CPB, at 6, 12 and 24 hours postop) for infants and pre- and post-pubertal children at and 6 timepoints for neonates (post-CPB sample excluded)
4. FSH, LH and testosterone or estradiol, measured by taking blood samples for 10-16 year olds only (pre-operative – before anaesthesia induction)
5. Death, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
6. Preoperative biventricular function, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
7. Cardiac arrest, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
8. Extracorporeal membrane oxygenation use, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
9. Renal insufficiency (creatinine more than two times normal), measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
10. Hepatic insufficiency, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
11. Duration of mechanical ventilation post cardiac surgery, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
12. Inotrope and vasopressors use, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge

13. Intensive care unit stay, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
14. Hospital stay, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
15. Infection, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
16. Insulin use, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
17. Fluid retention (daily weights), measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge

For the cardiac investigation cohort:
1. Adreno-corticotrophic hormone (ACTH), measured by taking blood samples at 1 timepoint (pre-operative)
2. Cortisol Binding Globulin (CBG), measured by taking blood samples at 1 timepoint (pre-operative)
3. IL-1, IL-4, IL-6, IL-8, IL-10 and TNF-alpha, measured by taking blood samples at 1 timepoint (pre-operative)
4. FSH, LH and testosterone or estradiol, measured by taking blood samples for 10-16 year olds only (pre-operative - before anaesthesia induction)
5. Death, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
6. Preoperative biventricular function, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
7. Cardiac arrest, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
8. Renal insufficiency (creatinine more than two times normal), measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
9. Hepatic insufficiency, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
10. Hospital stay, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
11. Infection, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge
12. Insulin use, measured using specially designed CRFs (case report forms) collecting data from the date of surgery until discharge

Overall study start date
01/05/2015

Completion date
01/12/2022

Eligibility

Key inclusion criteria
Inclusion criteria for the cardiac surgery cohort:
Participant may enter study if ALL of the following apply:
1. Age 0-5 or 10-16 years
2. Undergoing cardiac surgery using CPB
3. Weight above 2 kg for neonate patients

Inclusion criteria for the cardiac investigation cohort:
Participant may enter study if ALL of the following apply:
1. Age 0-5 or 10-16 years
2. Undergoing minimally invasive cardiac investigation with anaesthesia
3. Weight above 2 kg

The aim is to recruit patients in each of the following categories:
1. Infants
2. Age 1-5
3. Age 10-16

Participant type(s)
Patient

Age group
Mixed

Lower age limit
0 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
60

Total final enrolment
52

Key exclusion criteria
1. Emergency investigation
2. Current or recent (within 3 months) use of glucocorticoids
3. Disorders of the HPA axis
4. Thyroid disease

Date of first enrolment
14/09/2017

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Bristol NHS Foundation Trust
Bristol Royal Hospital for Children
24 Upper Maudlin St
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Royal Brompton Hospital
Sydney St
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Research & Innovation, University Hospitals Bristol NHS Foundation Trust
Level 3, Education & Research Centre
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/research-innovation/

ROR
https://ror.org/04nm1cv11

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
The protocol can be made available on request from Mr Jonathan Evans. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date
01/08/2022

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.
(added 12/12/2023): Data will not be made available for sharing until after publication of the main results of the study. Thereafter, anonymised individual patient data will be made available for secondary research, conditional on assurance from the secondary researcher that the proposed use of the data is compliant with the MRC Policy on Data Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the secondary research, e.g. a protocol for a Cochrane systematic review.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/12/2020	28/05/2020	Yes	No
HRA research summary			20/09/2023	No	No
Plain English results	version 1.0		08/03/2024	No	Yes