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Aetiology of preoperative anaemia in cardiac surgery

Submission date
11/12/2011

Recruitment status
No longer recruiting

Registration date
23/01/2012

Overall study status
Completed

Last Edited
27/07/2015

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Red Blood Cells (RBCs) are essential for carrying oxygen around the body via the bloodstream. Anaemia occurs when there is a reduction in the number of RBCs in the blood, meaning that less oxygen is available in the bloodstream. Pre-existing anaemia is an important and common health problem for patients presenting for elective heart surgery. It is associated with an increased requirement for blood transfusion, postoperative complications and death. Anaemia may be due to a variety of causes, with different types of anaemia requiring different treatments. However, identification of anaemia is often difficult using blood tests alone. Bone marrow analysis will improve the accuracy of the investigation to identify the cause of anaemia in these difficult situations. This is because RBCs are made in the bone marrow, which is found inside bones. Bone marrow analysis allows us to directly examine the number, condition and content of the predecessor cells which later develop into mature RBCs. In practice bone marrow biopsy is rarely performed because it is an invasive procedure. Currently there is little information on the cause of preoperative anaemia in heart surgery patients.
The main aim of this study is to accurately determine the causes of preoperative anaemia using both blood tests and bone marrow analyses in anaemic patients scheduled to have heart surgery at Papworth Hospital. Heart surgery provides a unique and convenient opportunity to obtain bone marrow sample from the breast bone (sternum). This is because the patients' sternums are routinely opened (sternotomy), whilst under general anaesthetics, by the heart surgeons to access the hearts during surgery. We will also determine the relative frequency and likely outcome of the different types of anaemia, and the treatments required to correct anaemia before surgery. This information will be used in a follow-up study looking at different treatments for preoperative anaemia. Correcting preoperative anaemia may lead to a reduction in blood transfusion and improved postoperative outcome for patients.

Who can participate?
To take part the patients need to be:
1. 18 years or older
2. Scheduled to undergo elective heart surgery requiring artificial heart-lung machine (cardiopulmonary bypass)
3. Anaemic before surgery (haemoglobin <13g/dL for men and <12 g/dL for women on admission)

What does the study involve?
This is an observational study of 200 elective heart surgical adults with preoperative anaemia. Management of the patients will not be altered as part of the study. All patients will have blood tests done before surgery, as part of the initial work up to identify the cause of the pre-existing anaemia. Small samples of bone marrow from the sternum will be collected using small needles in all patients immediately after sternotomy during surgery while patients are under general anaesthesia. Data regarding patient clinical information, transfusion, length of intensive care unit and hospital stay, severe kidney failure and death will be collected.

What are the possible benefits and risks of participating in the study?
The treatment of future patients may be improved and heart surgery may be made safer when we know the results of this study. There are no known risks to participants. Any participants with significant or unexpected investigation findings will be referred to haematologists for follow-ups.

Where is the study run from?
They study takes place at Papworth Hospital NHS Foundation Trust, Cambridge, UK.

When is the study starting and how long is it expected to run for?
Patient enrolment is expected to commence in January 2012 and it is expected to run for 7 months.

Who is funding the study?
Research and Development Unit, Papworth Hospital NHS Foundation Trust.

Who is the main contact?
Dr Andrew Klein
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Contact information

Type(s)
Scientific

Contact name
Dr Andrew Klein

Contact details
Department of Anaesthesia & Intensive Care
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CB23 3RE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective observational study to investigate the aetiology of preoperative anaemia in patients undergoing elective cardiac surgery

Study objectives
Preoperative anaemia is a highly prevalent and important health problem for cardiac surgical patients. It is associated with increased risk of blood transfusion and higher perioperative morbidity and mortality. Given the recognised risks associated with both anaemia and blood transfusion, the primary strategy to maintain an optimal perioperative haemoglobin level in these patients should include the correct diagnosis and successful treatment of preoperative anaemia before surgery takes place. Despite this, there is a paucity of data on the aetiology of preoperative anaemia in cardiac surgical patients. The findings from the study will indicate the relative frequency of the different causes of anaemia in cardiac surgical patients, and enable planning of appropriate treatment. This will assist in developing further research into the correction of anaemia before cardiac surgery, which may have a significant impact on clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee East of England - Norfolk, 15/06/2011, ref: 11/EE/0114

Study design
Observational 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Preoperative anaemia

Interventions
Standard preoperative blood test results will be noted. Additional blood will be taken for further tests. This forms the initial workup to determine the different causes of anaemia.
Intraoperatively at sternotomy, a small amount of bone marrow sample will be collected from the open sternal edge. The marrow sample will be sent to the pathology laboratory for histochemical analysis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To investigate the aetiology of preoperative anaemia, as defined by the WHO criteria, in adult patients undergoing scheduled cardiac surgery.

Secondary outcome measures
1. To gain information on the relative frequency and prognostic implications of the different types of preoperative anaemia
2. To assess the validity of the blood based tests in distinguishing the different types of preoperative anaemia
3. To devise a diagnostic algorithm and therapeutic regimes required for assessing and correcting anaemia before cardiac surgery takes place

Overall study start date
01/01/2012

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Consecutive patients, 18 years or older, scheduled to undergo elective cardiac surgery requiring cardiopulmonary bypass, who are anaemic at preoperative testing
2. Patients requiring:
2.1. First time or redo sternotomy
2.2. Coronary artery bypass grafting
2.3. Valve replacement or repair
2.4. Operation on the aorta

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 200

Key exclusion criteria
1. Hb ≥ 13 g/dL in men and ≥ 12 g/dL in women at preoperative testing
2. Emergency (non-scheduled) surgery

Date of first enrolment
01/01/2012

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital (UK)

Sponsor details
Research & Development Unit
Papworth Everard
Cambridge
England
United Kingdom
CB23 3RE

Sponsor type
Hospital/treatment centre

Website
http://www.papworthhospital.nhs.uk/index.php

ROR
https://ror.org/05mqgrb58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Research and Development Unit, Papworth Hospital, Cambridgeshire (UK)

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?
Results article	results	01/01/2015		Yes	No