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An observational study to determine the impact and effect of preoperative anaemia management in cardiac and vascular surgical patients: the UK CAVIAR Study

Submission date
06/06/2016

Recruitment status
No longer recruiting

Registration date
21/07/2016

Overall study status
Completed

Last Edited
31/12/2021

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Anaemia is a condition where a person does not have enough red blood cells or haemoglobin (the iron-containing protein in blood that binds to oxygen) to carry enough oxygen around their body. It is common in patients undergoing surgery on their heart (cardiac) and/or blood vessels (vascular). Being anaemic may increase the need for a blood transfusion after surgery. In patients who are unwell and requiring surgery, it is not known what the cause of this anaemia is nor if this affects whether the person is suitable for surgery. Without understanding the cause of the anaemia or the effect this may have on an individual it is not currently possible to recommend specific treatments. There is considerable variation in the way patients are assessed before surgery and how they are managed during and afterwards in different regions of the UK. For example, there are some centres treating patients with anaemia before the operation (iron management) in an attempt to reduce the need for blood transfusion. However, it is not known who these treatments are most appropriate for or how they affect an individual before their operation. The aim of this study therefore is to assess how patients are managed before their operation in different UK hospitals to see if there is any variation or effect of anaemia on patient' s outcome from surgery.

Who can participate?
Adult patients who are having elective (planned) heart or blood vessel surgery.

What does the study involve?
In this study the normal pathways of care patients receive in different hosptials are observed, and there are no changes to planned surgery or how patients are managed by their surgeon /consultant. Patients are identified through routine clinical care and are categorised into those who receive iron management and those who do not, as part of their normal care. For all participants, medical history, medications, blood results, exercise test results (if applicable) and information gathered during and after surgery is collected. In addition, the research team take extra blood samples from patients (to measure haemoglobin levels), ask patients to complete

Quality of Life questionnaires, and follow up patients progress after discharge. A small number of patients who received treatment for iron management also have a total hemoglobin mass test (a more accurate measure of haemoglobin levels) and an exercise test before surgery and then 4-6 weeks later.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating in this study. There is a small risk of pain, discomfort or bruising when blood samples are taken.

Where is the study run from?
Royal Free Hosptial (London) and 16 other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
August 2015 to December 2017

Who is funding the study?
National Institute of Academic Anaesthesia (UK)

Who is the main contact?
Ms Marisa Chau

Contact information

Type(s)
Public

Contact name
Ms Marisa Chau

Contact details
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WC1E 6AU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02637102

Secondary identifying numbers
20538

Study information

Scientific Title
The UK CArdiac and Vascular surgery Interventional Anaemia Response study: An observational cohort study to determine the impact and effect of anaemia in patients awaiting vascular and cardiac surgery

Acronym
UK CAVIAR

Study objectives
The primary objective is to determine the impact and effect of iron deficiency in cardiovascular patients who are anaemic before surgery.

The secondary objectives are to:
1. Define 'Good Responders' and identify which markers of iron status are associated with a good response to intravenous iron
2. Gather data on change in cardiorespiratory status, haemoglobin mass measurements and markers of iron deficiency.
3. Observe patient outcomes following operation including Days Alive and Out of Hospital at 30 days.
4. Gather information about the feasibility of setting up these investigations in the preoperative setting to guide a future RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Westminster REC, 27/11/2015, ref: 15/LO/1569

Study design
Multi-centre case-control study with cohort sub-study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Specialty: Surgery

Interventions
Patients will be identified through routine clinical care (e.g. preadmission clinic, or surgical outpatient, etc.) and will be categorised into the two arms: control (patients who do not receive iron management) and study arm (patients who do receive iron management (i.e. IV iron)). In addition, a sub-set of patients in the study arm (Sub-study arm) will be asked to complete additional assessments (i.e. exercise testing and/or total haemoglobin mass test) to explore the effects of IV iron may have on patient's fitness and outcome.

Patients will be observed through normal pathways of care and there is no change to the planned surgery or how patients are managed by their surgeon /consultant. Majority of the data (e.g. medical history, medications, blood results, exercise test results (if applicable), intra- and postoperative information) will be collected from the patient's medical records. Apart from routine information, the study will, in addition:
1. Collect extra blood samples:
Control arm: One before and one after surgery
Study arm (and sub-study arm): One before and one after IV iron, and one after surgery
2. Complete Quality of Life questionnaires (i.e. Single Question Outcome Measure (SQOM), Multidimensional Fatigue Inventory-20 (MFI-20), and European Quality of Life (EQ-5D-5L))
Control arm: N/A
Study arm: One before and one after IV iron
Sub-study arm: One before and one after IV iron, and one at follow-up
3. Follow-up on patient's progress post-discharge
Sub-study arm perform total haemoglobin mass test (if applicable) and perform a repeat exercise test (CPET or 6MWT) after IV iron if an exercise test was conducted routinely at baseline (if applicable)

Variations in centres with and without anaemia management and patient's outcome post-surgery (e.g. transfusion needs, quality of life, cardiorespiratory status and total haemoglobin mass test (if applicable), etc.) will be examined, as well as the relationship between different markers of iron deficiency to the change in outcome.

Total duration of observation: Until discharge after index operation, commencing from recruitment
Total duration of follow-up: Up to 30-45 days post-operation

Intervention Type
Other

Primary outcome measure
Haemoglobin is measured using blood testing at baseline, before surgery (within 10-42 days), and within 3 weeks post-surgery.

Secondary outcome measures
1. Biomarkers of iron deficiency (e.g. hepcidin, ferritin, TfSats) are measured using blood testing from baseline and after IV iron (within 4-6 weeks before surgery)
2. Unit of blood transfused during hospital stay (within 7 days) is measured through medical record review
3. ICU and hospital length of stay (within 30 days) is measured through medical record review
4. Renal function is assessed by measuring creatinine concentration at baseline, before surgery

(within 10-42 days) and post-surgery (within 3 weeks)
5. Complication rate within 30 days post-surgery is measured through medical record review
6. Recruitment rate is determined by the number of consented eligible participants within one year, as assessed by observations of the research and hospital staff team
7. Quality of Life questionnaires (i.e. EQ-5D-5L, multi-fatigue inventory (MFI), and Single question outcome measure (SQOM) at baseline, after IV iron (within 4-6 weeks before surgery) and post-surgery (within 3 weeks)

Sub-study only:
1. Total hemoglobin mass is measured using the total haemoglobin mass test at baseline and after IV iron (within 4-6 weeks before surgery)
2. Physical fitness is measured using functional exercise testing (CPET or 6MWT) at baseline and after IV iron (within 4-6 weeks before surgery)

Overall study start date
01/08/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Male and female adults aged 18 years or older
2. Screening [Hb] < 120 g/L (for females) or < 130g/L (for males)
3. Undergoing elective cardiac OR vascular surgery:
3.1. Coronary artery bypass (CABG), or valvular surgery, or combined CABG and valve surgery.
3.2. Repair or replacement of thoracic or abdominal aorta (open or endovascular)
4. Able to provide informed consent
5. Able to perform CPET or 6MWT if consented to take part in the sub study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 432; UK Sample Size: 432

Total final enrolment
228

Key exclusion criteria

1. Pregnancy or lactation
2. Adults with known underlying history of learning disabilities, or adults who do not have mental capacity to consent for themselves
3. Prisoners
4. Renal dialysis (current or planned within the next 12 months)

Date of first enrolment
01/03/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Papworth Hospital
Papworth Everard
Cambridge
United Kingdom
CB23 3RE

Study participating centre
Cardiff and Vale University Health Board
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Liverpool Heart and Chest Hospital
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Study participating centre
Castle Hill Hospital
Castle Road
Cottingham
United Kingdom
HU16 5JQ

Study participating centre
The Essex Cardiothoracic Centre
University Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Manchester Royal Infirmary
Oxford Road
Manchester

United Kingdom
M13 9WL

Study participating centre
St. Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Royal Oldham Hospital
Rochdale Road
Oldham
Manchester
United Kingdom
OL1 2JH

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Royal Cornwall Hospital
2 Penventinnie Lane
Treliske
Truro
United Kingdom
TR1 3LQ

Study participating centre
Royal Bournemouth Hospital
Castle Lane East
Bournemouth
United Kingdom
BH7 7DW

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Leicester Royal Infirmary Hospital
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University College London

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149 Tottenham Court Road
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W1T 7DN

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
National Institute of Academic Anaesthesia

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
Not provided at registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/04/2017		Yes	No
Results article		01/03/2020	31/12/2021	Yes	No
HRA research summary			28/06/2023	No	No