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Project title:	The UK CAVIAR Study: The UK CArdiac and Vascular surgery after Intravenous Iron Assessment of Response study
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Background:	Anaemia before cardiac or vascular surgery is common, and is present in up to one third of patients. Anaemic patients are more likely to suffer complications during and after surgery, including death (twice as likely), prolonged hospital stay (an extra two days), and blood transfusion (risk more than doubled). The most common cause of anaemia before surgery is iron *restriction*, where a patient has enough iron in their body but can't use it properly. This is due to changes in their metabolism due to chronic disease or ill health. Theoretically, this can be treated with an infusion of intravenous iron, which can now be safely given in 15 minutes as an outpatient, and increases haemoglobin in around two or three weeks, meaning it could be given before surgery without delaying it. However, its use before major cardiac or vascular surgery hasn't been properly tested before. **Primary Aim:** To determine if intravenous iron, when given routinely, to vascular and cardiac surgical patients who are anaemic before surgery, improves haemoglobin concentration (Hb) and to quantify the effect. **Aim 2:** To define 'Good Responders' and identify which markers of iron status are associated with response to intravenous iron defined by amount of increase in Hb per day pre-operatively. **Aim 3:** To gather data regarding change in cardiorespiratory status, hepcidin levels, acute kidney injury and outcomes following intravenous iron therapy to power a future multi-centre randomised controlled trial.
Methods:	CAVIAR is a prospective parallel cohort study. Consecutive patients who meet the inclusion criteria will be enrolled. A usual care comparison group consisting of patients who meet the inclusion criteria, but who due to logistical reasons are not able to attend the pre-operative anaemia clinic will be followed for comparison. As part of normal clinical assessment in the participating centres, patients scheduled for cardiac or vascular surgery, will be screened for anaemia immediately after the decision is made to proceed to surgery, and invited to attend for assessment and possible treatment in the pre-operative anaemia clinic, as per normal NHS practice in these

	hospitals. Following review in the clinic, enrolment in the study will be discussed and consent sought. Following informed consent, additional blood will be collected for analysis and health-related Quality of Life questionnaires will be completed on top of routine care. Depending on hospital protocol, if patients are admitted electively the day before, we will ask those patients to repeat their pre-operative cardiorespiratory assessment (CPET or 6 min walk test). Patients will receive IV iron if they meet the criteria on their hospital pathway. On admission to hospital the patient will have repeat blood tests, and health-related quality of life questionnaires performed. Details of surgery, postoperative recovery, hospital stay and any complications will be recorded.
Results: *If your study has **not** achieved its expected aims please could you explain why in this section and how you plan to adjust your study as a result.*	**Progress to date:** Over the past year, we have been undertaking ethics and R&D approvals. We have also decided to include non-anaemic patients, in addition to anaemic patients (with or without IV iron treatment) to compare the differences between patient groups. In addition, we have increased the recruitment number of those who don't get IV iron to take into account the time bias. This has been approved by REC. Therefore the total number of patients we will recruit for this study is 432. Patient recruitment has started in March 2016, with 17 cardiac and vascular sites participating in the study. Ten of the 17 sites are 'opened', with the remaining seven we anticipate to open within the next couple of months. To date, we have recruited 109 patients.
Diagrams / Figures	None
Please list any publication references resulting from your study	The protocol paper of this study is currently being prepared for submission.