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Can administration of iron supplement injection reduce blood transfusion rates in people with a low red blood cell count (anaemia) who are undergoing heart operation?

Submission date
18/12/2012

Recruitment status
No longer recruiting

Registration date
30/01/2013

Overall study status
Completed

Last Edited
14/08/2019

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
This study is comparing two different iron supplements for people with a low red blood cell count (anaemia) who are undergoing heart operation. Doctors know that people who have a low number of red blood cells (anaemia) before surgery can take longer to recover. This includes an increase need for blood transfusion after the operation and staying longer in intensive care. Previous studies investigating red blood cell (RBC) transfusion after heart operation have shown associations with pneumonia, wound infection and other severe bacterial infections. The aims of this trial are to find out: Effect of iron supplement injection as compared to iron tablets on the pre-operative haemoglobin levels; If an iron supplement injection can reduce blood transfusion; The effect on intensive care and in-hospital stay; The effect on post-operative complications

Who can participate?
You may be able to enter this trial if you: Are aged 50 years or older ; Have low red blood cells (anaemia) but do not need a blood transfusion ; Need a heart operation

What does the study involve?
Participants are randomly allocated (by computer) to one of two groups (this is called a randomised study). Neither you nor your doctor will be able to decide which group you are in. People in group 1 have iron (ferrous sulphate) tablets. You start taking these at least 14 days before your surgery.
People in group 2 have an iron supplement called Ferinject. You have Ferinject through a drip into a vein at least 3-6 weeks before your surgery.
The trial team will ask you to fill out questionnaires: Before you start treatment ; Just before your surgery; Between 6 and 8 weeks after surgery. This is called a quality of life study.
Taking part in this trial will not change the surgery you have. Your surgeon will discuss your operation with you. You will see the doctors and have some tests before you start treatment.

The tests include: Physical examination; Blood pressure recording ; Blood tests. You will have another blood test
; On the day of your operation ; A few days after your operation; And 6 to 8 weeks later.

What are the possible benefits and risks of participating?
You will benefit from closer monitoring of your blood count as well as the administration of iron supplements that would treat the anaemia that might otherwise have gone unnoticed until a later date nearer the operation. The treatment with iron injection may improve the anaemia and reduce the likelihood of needing a blood transfusion.
The inconvenience to participants has been kept to a minimum by scheduling the screening blood test to coincide with the routine surgical outpatient appointment. Consent and iron supplement injection as well as the questionnaires will all be administered at the time of the pre-operative admission clinic visit. The effect of the iron supplementation on haemoglobin levels will be assessed at the time of admission for surgery. Finally, the post-operative questionnaires will completed at the time of the post-op visit to the Out Patient Department. Hence patients will not need any additional hospital visit.
The most common side effects of Ferinject are:
Headaches
Feeling dizzy
Feeling and being sick
Diarrhoea
A rash
Stomach ache
The most common side effects of ferrous sulphate are:
Constipation
Upset stomach
Black stools

Where is the study run from?
The CIRTACS study has been set up by the Royal Wolverhampton NHS Trust (UK).

When is the study starting and how long is it expected to run for?
The CIRTACS trial is expected to start in the beginning of March 2013. The trial will take place in New Cross Hospital, Wolverhampton. You will be participating in the study for a minimum of 10 weeks and a maximum of 20 weeks. The trial will recruit 60 patients.

Who is funding the study?
This trial is sponsored by the Royal Wolverhampton NHS Foundation Trust with some external funding from Tripartite Award (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-005666-35

Protocol serial number
2012-003-0301-CARD

Study information

Scientific Title
Can intravenous iron reduce transfusion rates in anaemic patients undergoing cardiac surgery?

Acronym
CIRTACS

Study objectives
To assess the effect of pre-operative intravenous ferric carboxymaltose (Ferinject) therapy as compared to current practice (oral iron 200mg BD), on pre-operative haemoglobin levels in anaemic (Female <11.5g/dl or Male <12.5g/dl) patients undergoing elective cardiac surgery. Does its use lead to an increase in the patient's haemoglobin pre-surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Black Country NRES Committee, 02/01/2013

Study design
Pilot prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Use of iron supplement injection (Ferinject) in anaemic patients undergoing heart surgery.

Interventions
Anaemic patients undergoing elective cardiac surgery are consented to the trial will be given one of the following at pre-operative admission clinic (POAC)
1. Intravenous ferric carboxymaltose (Ferinject) in a single administration, in accordance with manufacturers instructions (Max dose:1000mg), will be administered over 30 minutes within the preoperative clinic. .A second dose will be given to those patients whos requirements are more tham 1000mg. Patients undergoing the infusion will have their pulse, blood pressure, temperature and oxygenation saturations monitored before and after the infusion and as indicated by their clinical picture. In case of any emergency, the same protocol will be followed as per for all patients attending the POAC.
2. Standard current practice (Oral iron 200mg bd). Currently no guidance on the preoperative management of anaemia is available. Current practice in these anaemic patients is to utilise allogenic blood transfusion in the pre-, peri- and postoperative period as and when indicated.
The CIRTACS trial is expected to start in the beginning of March 2013. The trial will take place in New Cross Hospital, Wolverhampton. Recruited patients will be participating in the study for a minimum of 10 weeks and a maximum of 20 weeks. The trial will recruit 60 patients.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
intravenous ferric carboxymaltose (Ferinject)

Primary outcome(s)
1. Haemoglobin (g/dl) increment after intravenous ferric carboxymaltose (Ferinject)
2. Proportion of patients achieving an increase in Haemoglobin level >1.5g/dl pre-op after intravenous ferric carboxymaltose (Ferinject)

Key secondary outcome(s))
1. Units of blood transfusion post-op (in theatre and CICU)
2. Duration of CICU and In-hospital LOS
3. Rates of post-operative complications (listed above)
4. Change in quality of life
5. Factors associated with anaemia and iron therapy i.e. serum ferritin, sTFR, iron, transferring, CRP, erythropoietin (EPO) and iron binding capacity, hepcidin
6. Cost savings

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Elective cardiac surgery
3. Pre-operative haemoglobin (Hb) level >1g/dl below the normal range (i.e. women <11.5g/dl and men <12.5 g/dl)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Pregnancy
2. Patient participating in another trial
3. Patients unable to give written consent
4. Patients with a recognised allergy or other contraindication to intravenous iron or related products
5. Low haemoglobin attributable to haemoglobinopathy
6. Anaemia secondary to known co-existing and uncorrected B12 or folate deficiency
7. Patients already receiving oral or intravenous iron treatment
8. Patients with evidence of significant symptomatic anaemia which would normally require urgent transfusion at the time of assessment
9. Patients with a Hb less than 9.0 g/dl

Date of first enrolment
01/03/2013

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cardiothoracic Surgery, Heart & Lung Centre
Wolverhampton
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WV10 0QP

Sponsor information

Organisation
Royal Wolverhampton Hospitals NHS Trust (UK)

ROR
https://ror.org/05pjd0m90

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Wolverhampton NHS Foundation Trust - Tripartite Award (UK)

Results and Publications

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 in British Society of Gastroenterology Annual General Meeting	01/07/2017		Yes	No
Results article	results	01/03/2019	14/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes