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Intravenous iron to treat anaemia following critical care

Submission date
16/07/2018

Recruitment status
No longer recruiting

Registration date
17/07/2018

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Anaemia is a reduction in the amount of haemoglobin in the blood. Haemoglobin is responsible for carrying oxygen in the blood. Anaemia is very common in patients during and after an intensive care unit (ICU) stay. Recent research has shown that that many patients who leave the ICU and subsequently the hospital with anaemia are still anaemic even up to 6 months after leaving hospital. Symptoms of anaemia include feeling tired (fatigue), lacking energy (lethargy), and shortness of breath. These symptoms are very common and distressing to ICU survivors and whilst these could be symptoms of anaemia they may also be related to other complications of having been ill in ICU. At present it is not known which is the best way to treat anaemia after ICU and as a result many patients do not receive any investigations or treatment for this. Recently, there have been a few small studies that suggest giving an injection of iron to patients that have spent time in ICU may be beneficial to their recovery, but more evidence is needed. The aim of this small study is to recruit around 130 participants across two large hospitals in Oxford and Edinburgh to see if a bigger study, involving hundreds more patients, is possible. The bigger study would test whether or not giving an injection of iron through a vein (intravenous) after ICU can treat anaemia (increase a patient's blood count) and make patients feel better when they are recovering at home.

Who can participate?
Adult patients who have been in the ICU for over 48 hours, are now deemed fit for discharge, and have low haemoglobin

What does the study involve?
Participants are randomly allocated to receive either iron through a vein (intravenous) or no iron. Extra blood samples (2-3 teaspoons worth) are taken to measure levels of iron and participants are asked to complete health questionnaires on three separate occasions: at the start of the study and after 28 and 90 days.

What are the possible benefits and risks of participating?
Potential benefits to patients include correction of anaemia with potential improvements in fatigue symptoms. Participants from both groups may benefit from increased observation, data collection and event monitoring as is common to other participants in research studies. The risks

of participating are the possible side effects of receiving intravenous iron. The most common reported side effects are nausea and headache. Other known side effects which may occur are dizziness, high blood pressure, and/or injection site reactions.

Where is the study run from?
1. John Radcliffe Hospital (UK)
2. Edinburgh Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
October 2017 to June 2020

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Akshay Shah
Akshay.shah@ndcls.ox.ac.uk

Study website
https://www.octru.ox.ac.uk/trials/trials-in-set-up/intact

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2018-000767-91

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38731

Study information

Scientific Title
INTACT: a randomised feasibility study of INtravenous iron versus usual care to Treat Anaemia in CriTical care survivors

Acronym
INTACT

Study objectives
The primary objective of this study is to assess the feasibility of a future large multicentre trial of intravenous iron to anaemia in survivors of intensive care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Berkshire B Research Ethics Committee, 07/07/2018, ref: 18/SC/0308

Study design
Randomised; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Anaemia

Interventions
Eligible participants will be randomised at the baseline visit to receive either intravenous iron or usual care using minimisation on a secure web-based system. Minimisation variables will include anaemia severity (Hb <80 g/l vs Hb 80 - 100 g/l) and ICU length of stay (<7 days vs ≥ 7 days)

Intervention group: Participants will receive a one-dose dose of intravenous ferric carboxymaltose (dose 1000 mg) as an infusion over a minimum of 15 minutes. This will be administered at any point between ICU and hospital discharge.

Control group: Participants will not receive intravenous iron from the research team. Any decision to commence iron therapy in this group would be at the discretion of the responsible clinical team and independent of the study.

Both groups will receive usual medical care.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Ferric carboxymaltose

Primary outcome measure
1. Recruitment and randomisation rates at baseline
2. Protocol adherence, defined as the number of participants allocated to the study drug who actually go on to receive it between randomisation and hospital discharge
3. Completeness of outcome data collection; completion of health-related quality of life (HRQoL) and healthcare resource use questionnaires at baseline and at 28 and 90 days post-randomisation

Secondary outcome measures
1. Clinical data on in-hospital mortality, length of stay and new infection will be collected from baseline to hospital discharge
2. Changes in laboratory haematological (e.g. haemoglobin) and iron profiles (e.g. ferritin) from baseline to 28 and 90 days post-randomisation
3. Changes in fatigue and HRQoL scores, using the MFI-20, FACIT-F and EQ-5D-5L questionnaires, from baseline to 28 and 90 days post-randomisation
4. Healthcare resource use (e.g. direct, indirect and total costs for the NHS from societal and payers perspective) measured using a bespoke questionnaire at 28 and 90 days post-randomisation

Overall study start date
03/10/2017

Completion date
01/06/2020

Eligibility

Key inclusion criteria

1. Adult ICU/HDU (Level 2 or 3) for ≥48 hours and now deemed fit for discharge by the attending physician
2. Last measured laboratory haemoglobin ≤100 g/l
3. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 130; UK Sample Size: 130

Total final enrolment
98

Key exclusion criteria
1. Planned palliative care
2. Planned home ventilation
3. Primary neurological diagnosis
4. Requirement for English translation
5. Known hypersensitivity to iron
6. Immunosuppressive therapy for organ transplant
7. Intravenous iron or erythropoietin in the previous 4 weeks
8. Weight < = 50 kg
9. Already enrolled into another trial where the trial protocol explicitly prohibits co-enrolment
10. Pregnancy (however, breastfeeding is not an exclusion criteria)
11. Personal or family history of iron overload disorders such as haemachromatosis or previously documented ferritin > 1200 ng.ml-1 and/or Tsat > 50%
12. History of severe asthma, eczema, or other atopic allergy
13. Chronic liver disease and/or screening Alanine Transferase / Aspartate Transferase x3 above upper limit of normal range
14. Haemodialysis dependent chronic kidney disease
15. Acute infection – non-resolving temperature > = 38°C within the past 24 hours or patient on non-prophylactic antibiotics
16. Patients residing outside a reasonable geographic follow-up area (e.g. defined as within approximately 30 miles of the John Radcliffe Hospital or Edinburgh Royal Infirmary)

Date of first enrolment
18/09/2018

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Oxford
United Kingdom
OX3 9DU

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

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office, Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: DRF-2017-10-094

Results and Publications

Publication and dissemination plan
The trialists plan to publish their study protocol in an appropriate peer-reviewed journal before study completion. They plan to publish their findings in a high-impact peer reviewed journal by June 2021.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study are available upon reasonable request from the Chief Investigator Dr Akshay Shah (akshay.shah@linacre.ox.ac.uk). These data are available until March 2025 after which they will be destroyed under current ethical approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/12/2021	08/12/2021	Yes	No
Protocol article		03/05/2021	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No