ISRCTN26088319 https://doi.org/10.1186/ISRCTN26088319

Red cell transfusion and QoL in myelodysplastic syndromes

Submission date 13/11/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/11/2014	**Overall study status** Completed	
Last Edited 26/01/2021	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-blood-transfusions-and-quality-of-life-in-people-with-myelodysplastic-syndrome

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17595

Study information

Scientific Title
Red blood cell transfusion thresholds and Quality of Life in myelodysplastic syndromes: a pilot, feasibility study

Acronym
REDDS

Study objectives
This pilot trial aims to find out if giving red blood cell transfusions to reach a higher haemoglobin concentration is possible, safe and would improve quality of life in patients with myelodysplastic syndromes (MDS). The results may help design a large multi-centre randomised, controlled trial to be conducted in the future, or may show that it is not possible to carry out such a trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford A, 11/09/2014, ref. 14/SC/1150

Study design
Randomised; Interventional; Design type: Not specified, Treatment

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Haematological Oncology; Disease: Myelodysplastic syndromes

Interventions
Transfusion Strategy, Eligible, informed and consented patients will be randomised to one of two red cell transfusion strategies:
1. Restrictive transfusion strategy to maintain haemoglobin concentration level between 85 and 100g/L; where 2 units of packed red cell unit transfusions are transfused when the haemoglobin concentration level is < 80g/L and 1 unit of packed red cell unit transfusions when haemoglobin concentration level is 80-85g/L.

2. Liberal transfusion strategy to maintain haemoglobin concentration; Study Entry : Single Randomisation only

Intervention Type
Biological/Vaccine

Primary outcome measure
The primary outcomes of this feasibility study, from day 0 to day 84, will be:
1. The percentage compliance of pre-transfusion haemoglobin concentrations being within or above the target range of the red cell transfusion threshold assigned
2. Achievement of at least a 20 g/L difference between the mean pre-transfusion haemoglobins in the liberal and restrictive strategy groups

Secondary outcome measures
1. Number of patients ineligible due to screening failure or workload of department
2. Enrolment rates defined as number of patients enrolled per month, number of replaced patients and patient tolerability of study schedule
3. Percentage compliance with completing the QoL questionnaires at scheduled study visits
4. Ability of patients to remain blinded to the treatment arm
5. Proportion of transfusions and proportion of patients with all transfusions given correctly, according to the algorithm
6. Percentage of pre-transfusion haemoglobin concentrations falling below, within and above the target range of the red cell transfusion threshold assigned
7. The magnitude of change in physical functioning, fatigue, dyspnoea and global health scores on the EORTC QLQ-C30 and calculated health utility on the EQ-5D comparing the two RBC transfusion thresholds, with clinically significant differences of 10 points for the QLQ-C30 and 0.08 points for the EQ-5D
8. Numbers of adverse events such as cardiac events and thromboembolic events, and transfusion reactions (as defined and adapted from SHOT definitions and as applied in other NHSBT CTU trials), per arm
9. The overall utilisation of blood during study period per group, to evaluate the amount of extra red cell units transfused/week/patient associated with the liberal strategy

Overall study start date
10/11/2014

Completion date
30/10/2018

Eligibility

Key inclusion criteria
1. All patients with MDS =18 years of age and with < 20% blasts on bone marrow aspirate (WHO classification), including non-proliferative CMML and other MDS/MPN overlap diseases. These patients will include both those recently diagnosed and with an established diagnosis
2. Transfusion dependent: at least 1 red cell transfusion episode per month in the last 8 weeks
3. Life expectancy >6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 38; UK Sample Size: 38; Description: 19 Patients in each arm (restrictive vs liberal transfusion strategy)

Total final enrolment
38

Key exclusion criteria
1 .Unable, in the opinion of the attending clinician, to tolerate restrictive or liberal red cell transfusion thresholds (e.g. clinically significant cardio-respiratory compromise)
2. Poor performance/functional status (Eastern Cooperative Oncology Group system ECOG =3)
3. Patients being actively treated with erythropiesis stimulating agents (ESAs) or disease modifying agents for their MDS (such as lenalidomide, azacitidine, hydroxycarbamide, experimental agents), as these may exert their own effects on the patients' quality of life and may render patients transfusion independent
4. Patients with myelofibrosis
5. Patients in whom the attending clinician considers that active bleeding or ongoing haemolysis contribute significantly to the cause of anaemia
6. Patients presenting with splenomegaly >5cm below the costal margin

Date of first enrolment
19/02/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Blood Service Oxford Centre
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
NHS Blood and Transplant (NHSBT)

Sponsor details
National R&D Office
500 North Bristol Park
Northway
Bristol
England
United Kingdom
BS34 7QH

Sponsor type
Hospital/treatment centre

Website
http://www.nhsbt.nhs.uk/

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
NHS Blood and Transplant (NHSBT) (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	01/04/2020	26/01/2021	Yes	No
HRA research summary			28/06/2023	No	No