ISRCTN96390716 https://doi.org/10.1186/ISRCTN96390716

Red cell transfusion in acute myeloid leukaemia (REAL)

Submission date 23/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2017	**Overall study status** Completed	
Last Edited 22/08/2022	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-when-to-give-blood-transfusions-for-acute-myeloid-leukaemia-real

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number
210454

ClinicalTrials.gov number

Secondary identifying numbers
31999

Study information

Scientific Title
REd cell transfusion in Acute myeloid Leukaemia (REAL)

Acronym
REAL

Study objectives
The aim of this study is to investigate the feasibility of conducting a multi-centre randomised, controlled trial comparing quality of life (QoL) at two haemoglobin (Hb) levels in patients with Acute Myeloid Leukaemia (AML).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/09/2016, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8191; NRESCommittee.WestMidlands-Solihull@nhs.net), ref: 16/WM/0406

Study design
Randomised; Interventional; Design type: Treatment, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Haematological Oncology; UKCRC code/ Disease: Cancer/ Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissu

Interventions

Participants will be randomly allocated to one threshold of haemoglobin for their first course of chemotherapy and the other for their second course. The 2 thresholds are; restrictive threshold (< = 70 g/L) and liberal threshold (< = 90 g/L). The study will run, for a each participant, for their first 2 courses of chemotherapy only (approximately 42 days per course). The participant would be randomised by an online randomisation system at www.sealedenvelope.com. Their randomisation result will be which arm of the trial they will be in for Cycle One of their chemotherapy treatment. The participant will cross over to the other arm for Cycle Two of their chemotherapy treatment.

Participants will be asked to fill in short questionnaires about their quality of life at certain intervals during their treatment. Each patient will be in the trial until end of their chemotherapy cycle 2 (approximately 3 months).

Intervention Type
Other

Primary outcome measure
1. Percentage of pre-transfusion haemoglobin concentrations being within target range of the assigned red cell transfusion strategy is measured using patient notes at pre every red cell transfusion
2. Achievement of at least a 15g/L difference between the mean pre-transfusion haemoglobins in the 2 randomisation groups is measured patient notes at pre every red cell transfusion

Secondary outcome measures
Adherence outcomes:
1. Transfusions given per protocol is assessed using patient notes and haemoglobin blood test results at the point of each transfusion
2. Red cell exposure is assessed using patient notes at the end of each cycle of chemotherapy
3. Adherence to outcome monitoring is assessed using review of trial case report forms data at time of forms arriving in CTU and at the end of the trial period
4. Recruitment rate is assessed using screening records at regular intervals
5. Characteristics of recruited participants are assessed using reviewing patient notes at the start of the trial

Clinical outcomes:
1. Bleeding rate is measured using number of severe bleeds reported at the end of each cycle of chemotherapy
2. Thrombosis rate is measured using number of thrombotic events reported at the end of each cycle of chemotherapy
3. Culture verified bacterial infections is measured using blood culture test results at the end of each cycle of chemotherapy
4. Platelet transfusion rate is measured using number of platelet transfusions recorded in patient notes at the end of each cycle of chemotherapy
5. Quality of Life (QoL) is measured using EQ-5D-5L and EORTC QLQ C30 questionnaires at 5 points during the study period (start of study, mid-cycle 1, between cycle 1 and cycle 2, mid cycle 2, end of study). Also only part b of the EQ-5D-5L will be daily assessed.
6. Transfusion reactions are measured using a transfusion reaction reporting form at each instance of a transfusion reaction.
7. Mortality rate is assessed using patient notes at 3 months after end of study

Compliance with data collection between sites is assessed using central monitoring of datasets received at point of receiving them and at point of adding the datasets to the database.

Primary outcome:
1. Percentage of pre-transfusion haemoglobin concentrations being within target range of the assigned red cell transfusion strategy is measured using patient notes and blood test results at each red cell transfusion
2. Achievement of at least a 15g/L difference between the mean pre-transfusion haemoglobins in the 2 randomisation groups is measured patient notes and blood test results at each red cell transfusion

Overall study start date
01/04/2016

Completion date
01/11/2019

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over
2. Diagnosis of de novo acute myeloid leukaemia (AML) or relapsed AML
3. Undergoing treatment with intensive chemotherapy with an expectation of receiving a minimum of 2 cycles (excluding stem cell transplant)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 36; UK Sample Size: 36

Total final enrolment
43

Key exclusion criteria
1. Patients for whom the attending haematologist feels allocation to either a restrictive or liberal policy of red cell transfusion is not justified (e.g. clinically significant cardiovascular disease)
2. Acute promyelocytic leukaemia (APML)
3. Patients who have been diagnosed with myelodysplasia prior to diagnosis of AML.

Date of first enrolment
14/02/2017

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
University Hospital Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
NHS Blood and Transplant

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Research organisation

Funder Name
NHS Blood and Transplant

Alternative Name(s)
National Health Service Blood and Transplant, UK National Health Service Blood and Transplant, NHSBT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results from different centres will be analysed together and published as soon as possible. Individual clinicians must not publish data concerning their patients that are directly relevant to questions posed by the study until the Trial Management Group has published its report and the main findings of the trial have been published. The Trial Management Group will form the basis of the Writing Committee and advise on the nature of publications. The main form of dissemination will be through publications including abstract presentations at meetings /conferences.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/02/2022	05/05/2022	Yes	No
Protocol file	version 2.0	09/10/2018	22/08/2022	No	No
HRA research summary			28/06/2023	No	No