

# Red cell transfusion in acute myeloid leukaemia (REAL)

<b>Submission date</b> 23/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/08/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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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 tissue

## 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 ( $\leq 70$  g/L) and liberal threshold ( $\leq 90$  g/L). The study will run, for 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](http://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

**Sponsor details**

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Filton

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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?
<a href="#">Results article</a>	version 2.0	16/02/2022	05/05/2022	Yes	No
<a href="#">Protocol file</a>		09/10/2018	22/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No