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Comparison of alternative strategies to assess haemoglobin levels in whole blood donors (COMPARE study)

Submission date
27/07/2015

Recruitment status
No longer recruiting

Registration date
13/10/2015

Overall study status
Ongoing

Last Edited
01/11/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Haemoglobin is an iron-containing protein found in red blood cells that carries oxygen around the body. Blood donor services have to measure haemoglobin levels in advance of each blood donation to protect the health of donors (e.g., to prevent anaemia) and to ensure the quality of blood products. NHS Blood and Transplant (NHSBT) measure the haemoglobin levels of donors using a crude but cheap method. A drop of donor's blood is put into a copper sulphate solution. If the drop sinks sufficiently, then it is judged that the donor's haemoglobin levels are high enough to donate. If the drop doesn't sink sufficiently, then a more accurate and costly test is used ("Hemocue"). No other blood service of a major industrialised country now uses this approach. Alternative methods used by other blood services may be more accurate, donor-friendly, and less time consuming. However, their comparative merits have not been investigated thoroughly. Here, we are going to do a survey of donors attending blood donation sessions across England to compare different strategies for haemoglobin testing. Results from this study should help to shape NHSBT (and international) policy concerning haemoglobin screening and to inform a major imminent procurement decision of NHSBT.

Who can participate?
Adults aged at least 18 from blood donation sessions across England.

What does the study involve?
Haemoglobin levels are measured with the current NHSBT method and with: i) a "post-donation" strategy, ii) Hemocue® on capillary blood, iii) a non-invasive strategy, and iv) a "gold standard" haemoglobin measurement. At the end of the study, we compare the accuracy of each strategy compared to the "gold-standard" haemoglobin measurement and NHSBT's current approach. Furthermore, we look at : (1) feasibility and acceptability of approaches for donors; (2) feasibility and acceptability of approaches for blood services staff; and (3) cost-effectiveness and operational impact for NHSBT.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit or risk to those taking part. NHSBT will continue to

follow its routine safety procedures to monitor haemoglobin level before donation. However, there should be benefits to future blood donors and to the country's future blood supply because the results of the study are likely to influence how the NHSBT screen for haemoglobin levels before blood donations.

Where is the study run from?
University of Cambridge in collaboration with NHS Blood and Transplant (NHSBT)

When is the study starting and how long is it expected to run for?
October 2015 to October 2025

Who is funding the study?
1. NHS Blood and Transplant (NHSBT)
2. University of Cambridge

Who is the main contact?
Dr Emanuele Di Angelantonio

Study website
http://www.comparestudy.org.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of NHSBT's current approach with three alternative strategies to assess haemoglobin levels in whole blood donors (COMPARE study)

Acronym
COMPARE

Study objectives
We aim to identify the optimum strategy to measure haemoglobin levels in potential whole blood donors in advance of each donation. The principal assessment will compare the current NHSBT screening method with three other alternative methods. We hypothesize that the current NHSBT method will involve a higher number of donors inappropriately bled donors than the other newer methods. The null hypothesis is that there are no differences across methods in the numbers of donors who would have been inappropriately bled.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge East, 18/12/2015, ref: 15/EE/0335

Study design
Multi-site observational study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Measurement of haemoglobin concentration of potential whole blood donors.

Interventions
We will compare the following three haemoglobin tests which are used by blood services in major Western industrialised countries against the results of a "gold standard" haematology analyser and against the results of the current NHSBT method:
1. A "post-donation" method: This method involves using haemoglobin levels obtained from a

“gold standard” haematology analyser at the most recent blood donation visit to predict the donor’s haemoglobin level at the next visit
2. A capillary point-of-care test: This method involves taking a drop of capillary blood after a finger-prick and measuring haemoglobin levels using a rapid Hemocue test
3. A non-invasive strategy: This method involves either of two hand-held spectrometer devices (ie, MBR Haemospect® versus Orsense NMB200®) that estimate haemoglobin levels by shining a light on the skin of a donor’s finger

Intervention Type
Mixed

Primary outcome measure
The primary endpoint will be the numbers of donors in the study who would have been inappropriately bled by each method (ie, donors who had haemoglobin levels <125g/L for women and <135g/L for men, according to European Union regulations). The principal assessment will compare the current NHSBT screening method with each of the three other alternative methods listed above. Specific measures to be calculated include false pass rate, sensitivity and specificity in detecting haemoglobin levels below the recommended cut-offs for whole blood donation.

Secondary outcome measures
We will study the following important and pre-specified secondary endpoints:

1. Differences in the numbers of donors who would have inappropriately bled when comparing the various newer methods to be studied with one another
2. Differences in the numbers of donors who would have been inappropriately bled when comparing the two non-invasive devices to be studied with each other
3. Feasibility and acceptability of different methods, according to the views of and blood services staff
4. Cost-effectiveness of different methods
5. Variability of the performance of different methods by donors’ personal characteristics
6. Medium and long-term health consequences of inappropriately bleeding at donation.
7. Biological mechanisms underlying personal characteristics (such as genetic profile) that may influence recovery of haemoglobin levels and iron metabolism after blood donation

Overall study start date
01/10/2015

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years and fulfilling all normal criteria for blood donation with the exception of pre-donation haemoglobin levels measured using the current NHSBT methods
2. Willing to undergo additional haemoglobin measurement
3. Willing to donate an extra blood sample for measurement of haemoglobin using an automated cell counter
4. Willing to come back for a subsequent appointment at standard donation interval (ie 12-wk and 16-wk for men and women respectively)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
31,000

Total final enrolment
29029

Key exclusion criteria
1. Participants who do not have internet access and/or are not willing to provide an email address for study correspondence (as the study will aim to be almost “paper-less” and will involve remote web-based data collection)
2. Donors already enrolled in the INTERVAL randomised trial will be excluded

Date of first enrolment
01/01/2016

Date of final enrolment
21/03/2017

Locations

Countries of recruitment
United Kingdom

Study participating centre
NHSBT - Blood donation mobile session
United Kingdom
-

Sponsor information

Organisation
NHS Blood and Transplant

Sponsor details
500 North Bristol Park
Northway
Filton
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
Not defined

Funder Name
NHS Blood and Transplant

Funder Name
University of Cambridge

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
17/03/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are/will be available upon request and approval from the COMPARE Data Access Committee [contact: helpdesk@comparestudy.org.uk].

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v5	05/07/2016	27/04/2021	No	No
Results article		01/04/2021	27/04/2021	Yes	No
HRA research summary			26/07/2023	No	No
Protocol file	version 6.1	22/02/2023	01/11/2023	No	No