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INTERVAL study: To determine whether the interval between blood donations in England can be safely and acceptably decreased

Submission date 29/11/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 25/01/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/08/2019	**Condition category** Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims
In order to ensure that there is enough supply of blood for hospitals and patients who need it, many people are asked to donate their blood. By giving blood, donors can help save lives. Blood donation is a very simple process, where a needle is inserted into a vein in the arm and around a pint of blood is collected. The entire process takes around five to ten minutes. However, there are often shortages in blood supply, especially for rare blood types. These shortages can be life threatening. One way to increase the blood supply is to ask previous blood donors to give more frequently, however donors must maintain enough time between donations in order to ensure their body replaces their blood iron levels. No one knows the ideal amount of time that should be waited between donations and the intervals between donations differ across countries. In England, the NHS Blood and Transplant team (NHSBT) invites men to donate every 12 weeks and women to donate every 16 weeks but in Europe some countries ask donors to donate every eight weeks. This study aims to recruit 50,000 blood donors to compare different intervals between blood donations. The goal is to find the optimum interval for which it is safe for different donors to give blood and to look at whether intervals should be tailored by age, gender, genetic profile, and other characteristics. The study's findings should help to improve the well-being of future blood donors in England and enhance the country's blood supplies.

Who can participate?
Adults over the age of 17 who attend an NHS blood donation clinic in England.

What does the study involve?
Participants are asked to join this study while they are at a blood donation clinic. Participants must pass the screening haemoglobin (blood iron) finger-prick test in order to give blood. Participants are randomly allocated to one of two groups. Those in the first group as asked to give blood at the usual donation intervals (based on their gender). Those in the second group are asked to donate blood more frequently. Men are asked to donate every eight, ten or 12 weeks and women every 12, 14 or 16 weeks. The study lasts two years in total. Participants are

asked to give an additional blood samples at the beginning and at the end of the study to test for the blood iron levels and for DNA. Participants also complete online questionnaires and assessments every six-months during the study period.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But 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 collects blood donations. The main risk of giving blood more frequently is iron deficiency and the related anaemia because of a low haemoglobin level. Therefore, NHSBT will continue to follow its routine safety procedures to monitor haemoglobin level before donation. Participants will receive the usual finger-prick screening test for haemoglobin levels and will need to be within the safe range to be eligible to donate.

Where is the study run from?
The INTERVAL study is being run by the Universities of Cambridge and Oxford and takes place in NHSBT blood donation clinics across England.

When is the study starting and how long is it expected to run for?
November 2011 to November 2021

Who is funding the study?
NHS Blood and Transplant team (NHSBT) (UK)

Who is the main contact?
1. Prof. John Danesh
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2. Prof. David Roberts
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Contact information

Type(s)
Scientific

Contact name
Prof John Danesh

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01610635

Protocol serial number
11-01-GEN

Study information

Scientific Title
A randomised trial to determine whether the interval between blood donations in England can be safely and acceptably decreased

Acronym
INTERVAL

Study objectives
The number of donations made by English blood donors will be greater with reduced versus standard inter-donation intervals. The null hypothesis is that there will be no difference in donations between treatment groups; this may arise if reduced inter-donation intervals result in a greater number of donation deferrals (due to low haemoglobin) and/or an unacceptable burden to donors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge East, 16/02/2012, ref: 11/EE/0538

Study design
Two-year open randomised parallel-group multi-site trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Optimum intervals for blood donation

Interventions
The study will involve 25,000 male and 25,000 female whole blood donors recruited at donation visits to the 25 permanent NHSBT clinics across England. Participation will be over a two-year period.

Male participants will be assigned to standard 12-week vs. 10-week vs. 8-week inter-donation intervals and female participants to 16-week vs. 14-week vs. 12-week intervals.

Added 14/03/2017:
INTERVAL participants were recruited between June 2012 and June 2014, and were studied over a two-year period. Following ethical approval of a substantial amendment to the protocol, some donors (who had completed their 2-year participation) were invited to continue on their randomised donation frequency for an additional period of 6 months – 2 years, and were

randomised to receive either routine or more intensive reminders to attend for blood donation. This study extension will enable additional questions to be answered on the acceptability and sustainability of shorter donation intervals, as well as on the effectiveness of different appointment-reminder approaches.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Total blood collected after two years, expressed in units (470ml) per person per year

Key secondary outcome(s))
Assessed two years after recruitment and will include:
1. Donor quality of life using the SF-36 health survey (this is the key secondary outcome)
2. Number of donation 'deferrals' (i.e. temporary rejections) of donors due to low haemoglobin and other factors
3. Markers of iron status (serum ferritin and reticulocyte haemoglobin)
4. Cognitive ability (reasoning, attention and memory)
5. Levels of physical activity
6. Cost effectiveness
7. Donor attitudes, beliefs and values

Completion date
01/11/2021

Eligibility

Key inclusion criteria
1. Age >17 years and fulfilling all normal criteria for blood donation
2. Willing to be assigned to any of the study intervention groups
3. Registered at one of the permanent donation clinics at the time of enrolment

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Current exclusion criteria as of 22/05/2012:
1. As the aim of the study is to be almost paper-less, it will involve remote web-based data

collection. Hence, participants who do not have internet access and/or are not willing to provide an email address for study correspondence will be excluded

Previous exclusion criteria:
1. Donors who are providing extra samples to NHSBT at their initial visit (e.g. for the British bone marrow registry) as there will be insufficient blood left in the sample pouch for the collection of study samples
2. As the aim of the study is to be almost paper-less, it will involve remote web-based data collection. Hence, participants who do not have internet access and/or are not willing to provide an email address for study correspondence will be excluded
3. Donors who have been identified for special panels by NHSBT

Date of first enrolment
11/06/2012

Date of final enrolment
15/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
Department of Public Health and Primary Care
Strangeways Research Laboratory
Worts Causeway
Cambridge
United Kingdom
CB1 8RN

Sponsor information

Organisation
NHS Blood and Transplant (NHSBT) (UK)

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
NHS Blood and Transplant (ref: 11-01-GEN)

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

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

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2016		Yes	No
Results article	results	25/11/2017		Yes	No
Results article	extension study results	01/10/2019	07/08/2019	Yes	No
Protocol article	protocol	17/09/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes