

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/08/2019	Condition category Other	<input type="checkbox"/> 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 are 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

john.danesh@phpc.cam.ac.uk

2. Prof. David Roberts

david.roberts@ndcls.ox.ac.uk

Study website

<http://www.intervalstudy.org.uk>

Contact information

Type(s)

Scientific

Contact name

Prof John Danesh

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01610635

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

The patient information sheet is available on the trial website <http://www.intervalstudy.org.uk>

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2011

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

Age group

Adult

Sex

Both

Target number of participants

50,000

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**

England

United Kingdom

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)

Sponsor details

c/o Professor Marion Scott
National R&D Manager
500 North Bristol Park
Northway
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BS34 7QH

Sponsor type

Government

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

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

01/11/2022

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?
Protocol article	protocol	17/09/2014		Yes	No
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