ISRCTN18230024 https://doi.org/10.1186/ISRCTN18230024

Evaluating the efficiency and safety of varying frequency and volumes of plasma donation: A large-scale study to SHAPE NHSBT's Plasma donation strategies (SHAPE-Plasma)

Submission date
01/05/2025

Recruitment status
Recruiting

Registration date
15/07/2025

Overall study status
Ongoing

Last Edited
15/07/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The National Health Service Blood and Transplant (NHSBT) is developing a new supply of plasma to reduce dependence on imports and, more importantly, to create plasma-derived medicines that save and improve the lives of approximately 17,000 people in England each year. This follows the lifting of a decades-old ban in 2021 on using United Kingdom (UK) plasma, making it crucial to research how to ensure safe and efficient plasma donations after 25 years. One way to increase the UK plasma supply is by collecting plasma more often and in larger amounts from donors. However, any risks associated with more frequent and larger donations are not well understood. More research is needed to find the best and safest way to donate plasma.
The SHAPE-Plasma Study seeks to recruit approximately 6,500 plasma donors from NHSBT plasma centres in England to determine the best donation frequency, volume, and approaches to support long-term donor behaviour without affecting donor health.

Who can participate?
Eligibility criteria:
-Age ≥18 years and fulfilling all normal criteria for plasmapheresis donation.
-Willing to be assigned to any of the study's intervention groups and donate at those intervals for the study period.
-Willing to donate at one of the donation centres for the duration of the study.

What does the study involve?
-Participants will be asked to read and electronically sign the SHAPE-plasma study consent form.
-Participants will be asked in the consent form to state their height and weight so that we can calculate how much blood they have and work out how much plasma they can safely donate.
-Following their signed consent and confirmation of their height and weight, they will be randomly assigned into the following groups:
1. firstly, participants will be randomly assigned to one of three donation frequency intervals: 2 weeks, 4 weeks or 8 weeks and will be expected to adhere to the assigned donation frequency

during the trial period.
2. secondly, participants will be randomly assigned to either current practice volume of plasma (i.e. the amount of plasma NHSBT currently take, 560ml, 630ml or 700ml) or the new personalised volume plasma (i.e. a new personalised volume of plasma, 560ml, 600ml, 630ml, 660ml, 700ml or 800ml).
3. lastly, participants will be randomly assigned to either current practice of booking appointments (i.e. schedule their own appointment in the usual way within their assigned donation frequency) or the new in centre-reminder (i.e. you will be asked by a member of staff in the centre to book your next appointment on the NHSBT app while you are donating).
-Participants will provide samples of blood (up to 10ml, equivalent to about 2 teaspoons) for research purposes. These samples will be taken during the first donation after consenting and then again approximately 52 weeks later. These samples will be taken at the same time as routine donations.
-Participants will complete questionnaires online; approximately every 8 weeks participants will be asked to complete a questionnaire via an email link and will take approximately 10 minutes to complete. It will cover questions about a recent plasma donation experience and general wellbeing.
-We'll collect, store and analyse health information about participants (including accessing health, donor and other health-related records).
-Participants will agree in the consent form to be contacted in the future and possibly be invited to give more samples or be involved in other research (participants can accept and decline on a case-by-case basis).

What are the benefits and risks of participating?
There will be no immediate, direct benefit to participants. However, future plasma donors and the country's plasma donation efforts should benefit from this study, as it's results are likely to influence how NHSBT collects plasma donations. The risk of participants suffering harm as a result of taking part in the study is minimal. This study is designed to assess and minimise risks in plasma donation. Nevertheless, insurance is in place to provide compensation for any negligent harm caused by participation.

Where is the study run from?
The study has been set up by the Universities of Cambridge and Nottingham in collaboration with NHSBT. University of Cambridge sponsors the study. The study will take place at NHSBT plasma donation centres in England (Birmingham, Reading and Twickenham).

When is the study starting and how long is it expected to run for?
The feasibility is due to start in June 2025, with the main trial starting in August 2025. Participants involvement lasts 1 year, but researchers may continue to study health records for longer to support future research.

Who is funding the study?
Funding has been provided by NHSBT and The National Institute for Health and Care Research (NIHR) Blood and Transplant Research Unit (BTRU). Once funding stops, data collected during the study will be maintained, as a national collection, by the lead academic institution, the University of Cambridge, in partnership with NHSBT.

Who can I contact?
For general enquiries about the study:
Email: helpdesk@plasma-study.org.uk
Freephone: 0800 021 7182 (Mon–Fri: 09:00–16:00)
Website: www.plasma-study.org.uk

Address: SHAPE-Plasma Study Coordinator
Victor Phillip Dahdaleh Heart & Lung Research Institute,
University of Cambridge, Biomedical Campus, Cambridge, CB2 0BB

Study website
https://www.plasma-study.org.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Emanuele Di Angelantonio

ORCID ID
https://orcid.org/0000-0001-8776-6719

Contact details
Department of Public Health and Primary Care, Cardiovascular Epidemiology Unit, University of Cambridge
Victor Phillip Dahdaleh Heart and Lung Research Institute (HLRI), Biomedical Campus, Papworth Road, Trumpington
Cambridge
United Kingdom
CB2 0BB
+44 (0)1223748659
ed303@medschl.cam.ac.uk

Type(s)
Scientific

Contact name
Dr Hannah Williams

Contact details
Department of Public Health and Primary Care, Cardiovascular Epidemiology Unit, University of Cambridge
Victor Phillip Dahdaleh Heart and Lung Research Institute (HLRI), Biomedical Campus, Papworth Road, Trumpington
Cambridge
United Kingdom
CB2 0BB
+44 800 021 7182
hgw31@medschl.cam.ac.uk

Type(s)
Public

Contact name

Mrs Elisha Johnson

Contact details
Department of Public Health and Primary Care, Cardiovascular Epidemiology Unit, University of Cambridge
Victor Phillip Dahdaleh Heart and Lung Research Institute (HLRI), Biomedical Campus, Papworth Road, Trumpington
Cambrdge
United Kingdom
CB2 0BB
+44 800 021 7182
ejt70@medschl.cam.ac.uk

Type(s)
Public

Contact name
Miss Shannon Duthie

Contact details
Department of Public Health and Primary Care, Cardiovascular Epidemiology Unit, University of Cambridge
Victor Phillip Dahdaleh Heart and Lung Research Institute (HLRI), Biomedical Campus, Papworth Road, Trumpington
Cambridge
United Kingdom
CB2 0BB
+44 800 021 7182
sd888@medschl.cam.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
348298

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Rec Reference: 24/EE/0259

Study information

Scientific Title
Evaluating the efficiency and safety of varying frequency and volumes of plasma donation: A large-scale study to SHAPE NHSBT’s Plasma donation strategies (SHAPE-Plasma)

Acronym
SHAPE-Plasma

Study objectives
To conduct a powerful, pragmatic randomised trial embedded within NHSBT that will help to shape national plasma donation policies.

Primary Objective-
To determine the optimum frequency and volume of donations to maximise efficiency of plasma collection and safety of donors.

Secondary Objectives-
1. To evaluate behavioural interventions for donor retention that maximises plasma supply without unacceptably increasing potential complications.
2. To determine whether plasmapheresis donation can be tailored to donors based on demographic, ethnic, haematological, and lifestyle factors to maximise production of human plasma medicinal products.
3. To define the optimal strategy for monitoring donor's health.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/01/2025, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0259

Study design
Open randomized multi-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://www.plasma-study.org.uk/participant-information-leaflet/

Health condition(s) or problem(s) studied
Plasma donor health

Interventions
Three interventions in the domains of 'frequency', 'volume', and 'behaviour' will be tested. The 'frequency' intervention will assess the effects of three inter-donation intervals. The 'volume'

intervention will assess the effects of two approaches for volume assignment (chart-based groupings as in usual practice vs. personalised volume). The 'behavioural' intervention will assess the effects of BAU (donors can make their own appointment on the NHSBT app when they wish to) vs 'in centre reminder' policy (donors will be asked by a member of staff in the centre to book their next appointment on the NHSBT app while they are donating).

Intervention Type
Other

Primary outcome measure
The total plasma volume collected over one year will be expressed in millilitres per person per year. There will be no missing data for this outcome. Intervention effects will be assessed as differences in means between randomised groups (usual volume vs enhanced volume, inter-donation intervals and appointment booking method) using linear regression model adjusted for any significant two-way interactions of interventions. Subsidiary analyses will adjust for baseline characteristics (centre, sex, age).

Secondary outcome measures
1. Donors' well-being will be assessed by using a questionnaire at the baseline, during the study, and at the end of the study. The questionnaires assess donors' general physical and mental health, cognitive function, motivation for plasma donation, and their personality.
2. Clinical adverse outcomes will be recorded in NHSBT PULSE system during the study. Differences in incidence of vasovagal reactions, citrate toxicity, other serious events, and all adverse events will be compared between randomised groups using logistic regression model.
3. Laboratory markers will be assessed using blood samples taken from donors during procedures. The markers of interest are all items in full blood count, total protein, albumin, and Ig. Differences in means of these markers will be compared between randomised groups using linear regression model.
4. Interim analyses will be performed at 26 weeks to ensure donors' safety and to provide a prompt feed-back to this ever-changing programme. The outcome of the interim analyses will be the total plasma collected and number of adverse clinical outcomes recorded. Comparisons will be made according to allocated volume and frequency of donation.

Overall study start date
01/03/2023

Completion date
01/08/2027

Eligibility

Key inclusion criteria
1. Age ≥18 years and fulfilling all normal criteria for plasmapheresis donation.
2. Willing to be assigned to any of the study's intervention groups and donate at those intervals for the study period.
3. Willing to donate at one of the donation centres for the duration of the study.

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
6,875

Key exclusion criteria
Does not meet inclusion criteria.

Date of first enrolment
02/06/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Donor Centre
2nd Floor, 65 New Street
Birmingham
United Kingdom
B2 4DU

Study participating centre
Twickenham Donor Centre
Floor 8, Regal House, 70 London Road
Twickenham
United Kingdom
TW1 3QS

Study participating centre
Reading Donor Centre
Ground floor, Kennet Place, 121 Kings Road
Reading

United Kingdom
RG1 3ES

Sponsor information

Organisation
University of Cambridge

Sponsor details
Addenbrooke's Hospital, Hills Rd
Cambridge
England
United Kingdom
CB2 0SP
+44 1223 769291
Research_Governance@medschl.cam.ac.uk

Sponsor type
University/education

Website
http://www.cambridge.org/

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Hospital/treatment centre

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

Funder Name
National Institute for Health and Care Research (NIHR) Blood and Transplant Research Unit (BTRU) Donor Health and Behaviour

Results and Publications

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available from the corresponding author on reasonable request. Anonymous participant level data will be available upon request and approval by the Data Access Committee for the study. Applications can be requested by contacting CEU-DataAccess@medschl.cam.ac.uk, 01223 747226. Only relevant information/variables will be provided and the whole data set is unlikely to be released.

IPD sharing plan summary
Available on request