

# 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)

<b>Submission date</b> 01/05/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year
<b>Registration date</b> 15/07/2025	<b>Overall study status</b> Ongoing	
<b>Last Edited</b> 15/07/2025	<b>Condition category</b> Circulatory System	

## 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 NHTSB 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 NHTSB 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 its results are likely to influence how NHTSB 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 NHTSB. University of Cambridge sponsors the study. The study will take place at NHTSB 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 NHTSB 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 NHTSB.

#### Who can I contact?

For general enquiries about the study:

Email: [helpdesk@plasma-study.org.uk](mailto:helpdesk@plasma-study.org.uk)

Freephone: 0800 021 7182 (Mon–Fri: 09:00–16:00)

Website: [www.plasma-study.org.uk](http://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

## Contact information

### Type(s)

Principal investigator

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

348298

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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 NHTSB 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

## **Study type(s)**

Other

## **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 NHTSB 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 NHTSB app while they are donating).

## **Intervention Type**

Other

## **Primary outcome(s)**

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).

### **Key secondary outcome(s)**

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 NHTSB 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.

### **Completion date**

01/08/2027

## **Eligibility**

### **Key inclusion criteria**

1. Age  $\geq 18$  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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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**

United Kingdom

England

**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

**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

## 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@medsch.cam.ac.uk](mailto:CEU-DataAccess@medsch.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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes