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Capturing physiological responses to blood donation using a portable sensor

Submission date 23/11/2021	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/12/2021	**Overall study status** Completed	
Last Edited 29/06/2022	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Vasovagal reactions consist of symptoms like dizziness, sweating, pallor, and anxiety. They are among the most common adverse events seen in blood donation. They can cause donors distress, potential injury from falling and are a strong disincentive for donors to return, which affects the stability and safety of the blood supply. Once early symptoms of vasovagal reactions are noticed by donors or staff, it is often too late to avoid a number of complications.
Vasovagal reactions are inherently a stress-related response associated with fear and a variety of changes in autonomic arousal (e.g., the activity of the autonomic nervous system of the body – not associated with any medical condition; this activity is responsible for the body's processes, including heart rate and perspiration). As such, the prediction of vasovagal reactions may be improved by assessing autonomic activity throughout donation, including the pre-donation period.
The aim of this study is to assess the effectiveness and feasibility of continuous physiological measures during the complete donation process of assisting in the early prediction of vasovagal and other adverse reactions.

Who can participate?
Healthy adult volunteers who are giving their first whole blood or apheresis plasma donation at one of the participating donor centres.

What does the study involve?
All participants will be given a monitor to place on their finger to measure their autonomic activity (e.g. heart rate, perspiration) after they register for their donation appointment until they completed their donation and are resting in the refreshments area. This monitor will be accompanied by a tablet on which the participants are asked to provide timestamps throughout their appointment (e.g., the needle was inserted, the needle was removed). They will also be asked to complete a short survey before their donation interview and a longer survey after their donation about their donation experience and any vasovagal symptoms they may have felt.

What are the possible benefits and risks of participating?
There are minimal foreseeable risks associated with participating in the study, and the researchers don't expect the participant to experience any discomfort by taking part.

Participation in this study is completely voluntary, and there is no compensation for participating.

Where is the study run from?
Macquarie University (Australia)

When is the study starting and how long is it expected to run for?
February 2020 to May 2022

Who is funding the study?
Australian Red Cross Lifeblood (Australia)

Who is the main contact?
Dr Philippe Gilchrist
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2020#09

Study information

Scientific Title
Predicting vasovagal and other adverse events in Australian voluntary blood donors using a portable sensor that measures bio-signal data (PREVENT)

Acronym

PREVENT

Study objectives
Patterns of higher pre-donation skin conductance (SC) and sympathetic withdrawal (lower low frequency/high frequency [LF/HF] heart rate variability) will be associated with subsequent phlebotomist-recorded and self-reported symptoms of vasovagal reactions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2020, Australian Red Cross Lifeblood Ethics Committee (17 O'Riordan Street, Alexandria, NSW 2015, Australia; +61 (0)2 9234 2368; ethics@redcrossblood.org.au), ref: 2020#09

Study design
Multicentre observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Vasovagal/pre faint symptoms in voluntary whole blood and apheresis plasma donors

Interventions
Immediately after donor registration and providing consent, an ambulatory physiological monitor (e.g., the 'evu TPS' sensor; https://evutps.com/en/) will be attached to the participant's finger to monitor autonomic activity throughout donation, from the point of consent up until arrival at the refreshment area after donation, continuously measuring skin conductance response (and heart rate variability for exploratory analyses). The ambulatory monitor is a compact and lightweight portable sensor measuring bio-signal data from a small (i.e., ~3 cm x ~2 cm x~2 cm) device attached to a finger. The bio-signal is sent in real time via Bluetooth to a tablet for later analysis. The device will be removed after completing the blood donation at the refreshment area.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Self-reported vasovagal symptoms measured using the Blood Donation Reactions Inventory (BDRI) at the haemoglobin test, needle insertion, first red cell return (plasma only), saline administration (plasma only), needle removal, and post-donation
2. Donation fear measured using a single fear question pre- and post-donation

3. Venipuncture pain measured using a self-report post-donation
4. Donor anxiety measured using the Blood Donor Anxiety Scale post-donation
5. Donor satisfaction with biometric sensor device measured using a self-report post-donation

Key secondary outcome(s))
1. Staff-recorded vasovagal reactions measured using Australian Red Cross Lifeblood standard procedures at any point at the donation centre
2. Donor return measured using Australian Red Cross Lifeblood records at 6-month follow-up
3. Time taken to return measured using the donor's next attendance date as recorded by Australian Red Cross Lifeblood at 6-month follow up

Completion date
16/05/2022

Eligibility

Key inclusion criteria
1. Eligible to donate as per the Australian Red Cross Lifeblood Guidelines for the Selection of Blood Donors
2. Donating whole blood or plasma for the first time
3. Willing and able to provide informed consent
4. Has a plasma or whole blood appointment at one of the participating donor centres (appointment made as a walk-in donor or scheduled appointment)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
522

Key exclusion criteria
1. Unwilling or unable to provide informed consent
2. Lack of understanding of the English language necessary to complete questionnaires. This study will not use translation services or interpreters
3. Contacted for a research study in the last 6 months as per Lifeblood contact policy
4. Donors with therapeutic, autologous, sample or platelet donation appointments
5. Lifeblood employees

Date of first enrolment
23/11/2021

Date of final enrolment
16/05/2022

Locations

Countries of recruitment
Australia

Study participating centre
Australian Red Cross Lifeblood Brisbane Donor Centre
288 Edward Street
Brisbane
Australia
4000

Study participating centre
Australian Red Cross Lifeblood Chatswood Donor Centre
Shop 62
Chatswood Interchange
436 Victoria Avenue
Chatswood
Australia
2067

Study participating centre
Australian Red Cross Lifeblood Parramatta Donor Centre
22-30 Oak Street
Rosehill
Australia
2142

Sponsor information

Organisation
Australian Red Cross Lifeblood

ROR
https://ror.org/00evjd729

Funder(s)

Funder type
Charity

Funder Name
Australian Red Cross Lifeblood

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date