ISRCTN23657907 https://doi.org/10.1186/ISRCTN23657907

Study of whole blood in frontline trauma

Submission date
18/11/2022

Recruitment status
No longer recruiting

Registration date
07/12/2022

Overall study status
Completed

Last Edited
17/03/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Every year, uncontrolled bleeding due to major injury (major traumatic haemorrhage) accounts for more than 2 million deaths worldwide and 4,500 deaths in England. Blood transfusion is an essential part of the treatment for severe bleeding, and any delay in starting transfusion can reduce the chances of survival. In the UK patients are often transfused blood at the scene of an incident before they arrive at hospital. Transfusion may involve different blood components, red blood cells (important for carrying oxygen around the body), plasma (contains essential proteins to help blood clot) and platelets (small cells that are essential for blood clot formation). Most UK air ambulances treat bleeding patients with a combination of red blood cells and plasma, which come in separate bags. However, carrying separate blood component bags introduces logistical challenges due to the additional weight the team needs to carry; increased complexity as several bags may need to be given to each patient; and a potential delay in transferring patients to hospital. Whole blood contains red cells, plasma and platelets all in one bag, as taken from a blood donor. Giving a blood transfusion of all of the components in a single bag could overcome these challenges. The aim of this study is to assess the clinical and cost-effectiveness of pre-hospital whole blood administration versus standard care for traumatic haemorrhage.

Who can participate?
Patients of any age who have suffered a traumatic injury, attended by a participating Air Ambulance Service clinical team, who require pre-hospital blood transfusion to treat major traumatic haemorrhage.

What does the study involve?
In this study, one group of patients will be given transfusions of red blood cells and plasma. The other group of patients will receive transfusions of whole blood. The effects of the two different treatments will be compared by looking at survival in the two groups and the amount of blood needed over the first 24 hours after injury. At the end of the study the researchers will determine which of the transfusion types is better (or whether there is no difference between them), and the cost-effectiveness and safety of giving whole blood transfusions compared to red blood cells.

What are the possible benefits and risks of participating?
There are no known risks or benefits linked to/attributed to taking part in this study, and there are no known additional risks in participating in the study compared to the risk associated with

transfusing blood components. Information collected as part of this trial may benefit patients in the future.

Where is the study run from?
NHS Blood and Transplant Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
March 2020 to June 2025

Who is funding the study?
The study has been funded by NHS Blood and Transplant, the Ministry of Defence and the following Air Ambulance Services:
1. Air Ambulance Kent Surrey Sussex (AAKSS)
2. Dorset and Somerset Air Ambulance (DSAA)
3. Essex and Herts Air Ambulance (EHAAT)
4. Hampshire and Isle of Wight Air Ambulance (HIOWAA)
5. Great North Air Ambulance (GNAAS)
6. Great Western Air Ambulance (GWAAC)
7. London's Air Ambulance (LAA)
8. Magpas Air Ambulance (Magpas)
9. North West Air Ambulance (NWAA)
10. Thames Valley Air Ambulance (TVAA)

Who is the main contact?
NHS Blood and Transplant Clinical Trials Unit, swift@nhsbt.nhs.uk

Study website
https://www.nhsbt.nhs.uk/swift

Contact information

Type(s)
Public

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2021-006876-18

IRAS number
300414

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52435, IRAS 300414

Study information

Scientific Title
A multi-centre randomised controlled trial of the clinical and cost-effectiveness of pre-hospital whole blood administration versus standard care for traumatic haemorrhage

Acronym
SWiFT

Study objectives
Pre-hospital leukocyte-depleted whole blood transfusion is better than standard care (component transfusion) in reducing the proportion of participants who experience death or massive transfusion at 24 hours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2022, South Central - Oxford C Research Ethics Committee (Health Research Authority (Bristol), Ground Floor, Temple Quay House, 2 The Square, BS1 6PN, UK; +44 (0)207 104 8241, oxfordc.rec@hra.nhs.uk), ref: 22/SC/0072

Study design
Randomized treatment process-of-care management-of-care health-economic study

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Traumatic haemorrhage

Interventions
Study design
A randomised controlled trial of pre-hospital whole blood versus red blood cells and plasma (non-blinded), for the treatment of major traumatic haemorrhage.

Type of participant to be studied
Patients (of any age) who require a blood transfusion in the pre-hospital setting, for the treatment of major traumatic haemorrhage.

Setting
Pre-Hospital Emergency Medicine.

Randomisation
Randomised boxes containing the trial intervention (either two units of whole blood or two units of red blood cells and two units of plasma) will be prepared in advance by the Transfusion Laboratory Teams. The boxes will be supplied to the participating Air Ambulance Services. If they attend to a patient who has suffered major trauma and requires blood transfusion, the team will open the trial intervention box and administer the contents to the patient, in accordance with standard local blood transfusion protocols. The time that the box was opened will be recorded and referred to as the randomisation time for the purposes of follow-up data collection. Informed consent will not be obtained prior to the initiation of treatment, due to the life-threatening nature of the patient's condition. Patients will be enrolled under an emergency waiver of consent, and informed consent will be sought (either directly from the participant, if they have capacity, or via a representative) as soon as practically possible.

Treatment
The intervention arm will be up to two units of whole blood (www.transfusionguidelines.org/red-book/annex-3/a3-6-whole-blood-leucocyte-depleted-for-clinical-studies). The control arm will be up to two units of red blood cells and up to 2 units of plasma (this is the current standard of care for the participating Air Ambulance Services). The plasma used in the control arm will either be fresh-frozen plasma (FFP) or LyoPlas (freeze-dried plasma). LyoPlas is classified as an IMP as it involves a manufacturing process. All other products used in this trial are blood components and fall under The Blood Safety and Quality Regulations. If bleeding continues after the trial

intervention(s) have been administered, participants will receive further treatment as per standard of care.

Follow-up of participants
Patients will be reviewed as per standard clinical care. Data will be collected for the trial, for the secondary outcome measures, up to 90 days post-randomisation.

Safety reporting
Serious adverse events will be documented and reported up to 14 days post-treatment. The protocol lists events which are excluded from reporting (i.e. those which are recognised complications and consequences of major trauma).

Qualitative research
Alongside the randomised controlled trial, an 'implementation study' will be conducted. This will assess the acceptability and implementation of the intervention (whole blood). In this sub-study, qualitative methods will be used, involving interviews and focus groups with operational staff, patient representatives and blood donors.

Intervention Type
Other

Primary outcome measure
The proportion of participants with traumatic haemorrhage who have died (all-cause mortality) or received a total of 10 or more units of any blood components in the first 24 hours from randomisation

Secondary outcome measures
Clinical Outcomes:
1. Individual components of the primary outcome: Proportion of participants who:
1.1. Experienced all-cause mortality at 24 hours from randomisation
1.2. Received a total of 10 or more units of any blood components in the first 24 hours of randomisation IV
2. All-cause mortality within 6 hours and separately 30 and 90 days of randomisation IV
3. Number of organ failure free days up to 30 days after randomisation, defined as the number of days free of advanced cardiovascular, advanced respiratory and advanced renal support. Each component of organ failure-free days will also be reported separately:
3.1. Number of days free of advanced respiratory support
3.2. Number of days free of advanced cardiovascular support
3.3. Number of days free of advanced renal support
4. Days in critical care and separately in an acute care hospital (up to 90 days)
5. Units of each blood component received in the 24 hours after randomisation IV (including prehospital transfusions): whole blood (WB) and red blood cells (RBC), plasma, platelets and cryoprecipitate
6. Amount of cell salvage received at 24 hours (in ml) after randomisation IV
7. Number of participants receiving additional haemostatic agents received at 24 hours after randomisation IV: recombinant Factor VIIa, fibrinogen concentrate, prothrombin complex concentrate (PCC), tranexamic acid (TXA)
8. Presence of coagulopathy (defined as prothrombin time above the limits of a normal range) in the first sample taken on arrival at an acute care hospital
9. Acid-base disturbance measured by lactate, base excess and pH level in the first sample taken on arrival at an acute care hospital

Cost-Effectiveness Analysis Outcomes:
1. Incremental cost of the whole blood intervention
2. Hospital resource use to discharge or death
3. Health, social and wider care resource use to 90 days after randomisation
4. Health-related quality of life measured by EQ-5D-5L at 90 days after randomisation

Safety Outcomes:
1. Thrombosis (arterial and venous thrombosis) up to 30 days after randomisation
2. All transfusion reactions/events relating to pre-hospital blood components which have been reported to SHOT (Serious Hazards of Transfusion) occurring in the first 14 days after randomisation

Overall study start date
01/03/2020

Completion date
01/06/2025

Eligibility

Key inclusion criteria
1. Patient (of any age) who has suffered a traumatic injury
2. Attended by a participating Air Ambulance Service (AAS) clinical team
3. Requires pre-hospital blood transfusion to treat major traumatic haemorrhage

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
Planned Sample Size: 848; UK Sample Size: 848

Key exclusion criteria
1. No intravenous or intraosseous access
2. Knowledge that the patient will object to being given blood transfusion for any reasons
3. Blood already administered on-scene, prior to the arrival of the participating Air Ambulance team

Date of first enrolment
15/12/2022

Date of final enrolment
12/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Kent, Surrey & Sussex Air Ambulance Trust
Rochester City Airport
Maidstone Road
Chatham
Kent
United Kingdom
ME5 9SD

Study participating centre
Alder Hey Children's Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
Bristol Royal Hospital for Sick Children
St. Michaels Hill
Bristol

United Kingdom
BS2 8BJ

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Dorset and Somerset Air Ambulance
Henstridge Airfield, the Marsh
Henstridge
Templecombe
United Kingdom
BA8 0TN

Study participating centre
Dorset County Hospital
Dorset County Hospital
Princes Street
Dorchester
United Kingdom
DT1 1TS

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Essex & Herts Air Ambulance Trust
Flight House
Earls Colne Business Park
Colchester
United Kingdom
CO6 2NS

Study participating centre
The Great North Air Ambulance Service
Progress House
Urlay Nook Road
Eaglescliffe
Stockton-on-tees
United Kingdom
TS16 0QB

Study participating centre
Great Western Air Ambulance Charity
County Gates
Ashton Road
Bristol
United Kingdom
BS3 2JH

Study participating centre
Hampshire & Isle of Wight Air Ambulance Air Base
Hangar 2
Thruxton Airfield
Thruxton
Andover
United Kingdom
SP11 8PW

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
London's Air Ambulance
5th Floor
77 Mansell Street
London
United Kingdom
E1 8AN

Study participating centre
Magpas The Emergency Medical Charity
Centenary House
St. Marys Street
Huntingdon
United Kingdom
PE29 3PE

Study participating centre
Manchester Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
North West Air Ambulance
North Mersey Business Centre
Woodward Road
Knowsley
United Kingdom
L33 7UY

Study participating centre
Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
The Royal London Hospital
Alexandra House
London
United Kingdom
E1 1BB

Study participating centre
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
Southampton General Hospital
Tremona Road

Southampton
United Kingdom
SO16 6YD

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
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United Kingdom
BS10 5NB

Study participating centre
St Georges Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
St Marys Hospital
The Bays
South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
Thames Valley Air Ambulance (oxford Road)
Stokenchurch House
Oxford Road
Stokenchurch
High Wycombe
United Kingdom
HP14 3SX

Study participating centre
University Hospital (coventry)
Clifford Bridge Road

Coventry
United Kingdom
CV2 2DX

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
NHS Blood and Transplant

Sponsor details
500 North Bristol Park
Northway
Filton
Bristol
England
United Kingdom
BS34 7QH
+44 (0)7590352169
research.office@nhsbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nhsbt.nhs.uk/

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

NHS Blood and Transplant; Grant Codes: 21-102-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

Funder Name
Ministry of Defence

Alternative Name(s)
MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Air Ambulance Kent Surrey Sussex (AAKSS)

Funder Name
Dorset and Somerset Air Ambulance (DSAA)

Funder Name
Essex and Herts Air Ambulance (EHAAT)

Funder Name

Hampshire and Isle of Wight Air Ambulance (HIOWAA)

Funder Name
Great North Air Ambulance (GNAAS)

Funder Name
Great Western Air Ambulance (GWAAC)

Funder Name
London’s Air Ambulance (LAA)

Funder Name
Magpas Air Ambulance (Magpas)

Funder Name
North West Air Ambulance (NWAA)

Funder Name
Thames Valley Air Ambulance (TVAA)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, at scientific conferences and publication on (study) website

Intention to publish date
01/12/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	03/05/2022	02/12/2022	No	No
HRA research summary			20/09/2023	No	No
Protocol article	RCT protocol	14/11/2023	16/11/2023	Yes	No
Protocol article	Implementation study protocol	05/02/2024	06/02/2024	Yes	No