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A study to define the platelet count below which critically ill patients should receive a platelet transfusion before an invasive procedure

Submission date 01/09/2022	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 30/09/2022	**Overall study status** Ongoing	
Last Edited 20/04/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Platelets are cells in the blood that help form clots and stop bleeding. People treated in a critical care unit often have a low number of platelets (platelet count) in their blood because they are very unwell. Platelet transfusions are made up of platelets collected from screened, healthy donors. Platelet transfusions are sometimes given before these procedures if the patient's platelet count is low. This is thought to reduce the possible risk of bleeding from the procedure. However, platelet transfusions also carry risks such as inflammation, infection, and allergic reactions, and may not work as effectively in unwell patients.
Currently, we do not know the platelet count below which giving a platelet transfusion might be beneficial. Surveys of doctors working in UK critical care units have shown uncertainty over the platelet count below which doctors should give a platelet transfusion. As a result, platelet transfusions are currently given to patients with a wide range of different platelet counts and there is no set threshold.
This study will test five different thresholds to find out the safest count below which platelet transfusions should be given before invasive procedures are carried out in intensive care.

Who can participate?
Patients aged 18 years and over who have accepted for admission or admitted to critical care, with a platelet count of less than 50 x 10e9/L who are being considered for a platelet transfusion for a low bleeding risk invasive procedure

What does the study involve?
Patients will be allocated to one of five platelet count thresholds (less than 10, 20, 30, 40 or 50). If their platelet count is below their allocated threshold, then they will receive a platelet transfusion before a low bleeding risk invasive procedure. Patients will remain in their allocated 'group' (threshold) for the duration of their critical care unit stay.
Some information about the patients' hospital stay is collected from hospital medical records. Other important health information is collected from national health databases. Some patients

will also be sent a short health questionnaire around 90 days and 1 year after becoming involved in the study. At the end of the study, all this information will allow us to compare the different transfusion thresholds in the study to find out which is most beneficial.

What are the possible benefits and risks of participating?
The benefit of receiving a platelet transfusion is to possibly reduce the risk of bleeding during an invasive procedure. The possible risks of receiving a platelet transfusion include inflammation, infection and allergic reactions. The purpose of this study is to look at the best platelet count threshold at which the possible benefits of platelet transfusion outweigh the possible risks, as this is currently unclear.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2027

Who is funding the study?
National Institute for Health Research (NIHR) – Health Technology Assessment Programme (UK)

Who is the main contact?
Hayley Noble, T4P@icnarc.org

Contact information

Type(s)
Scientific

Contact name
Ms Hayley Noble

Contact details
Intensive Care National Audit & Research Centre (ICNARC)
Napier House
24 High Holborn
London
United Kingdom
WC1V 6AZ
+44 (0)20 7269 9277
T4P@icnarc.org

Type(s)
Scientific

Contact name
Prof Peter Watkinson

ORCID ID
https://orcid.org/0000-0003-1023-3927

Contact details

Nuffield Department of Clinical Neurosciences
Kadoorie Centre for Critical Care Research and Education
The Chancellor Masters and Scholars of the University of Oxford
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 220 621
Peter.watkinson@ndcn.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
312405

Central Portfolio Management System (CPMS)
53274

Study information

Scientific Title
The Threshold for Platelets (T4P) study: a prospective randomised trial to define the platelet count below which critically ill patients should receive a platelet transfusion prior to an invasive procedure

Acronym
T4P

Study objectives
That platelet transfusion in critically ill patients has net clinical and monetary benefit only below certain thresholds where any gain of preventing bleeding exceeds harm from exacerbating inflammatory and/or infective processes.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 08/07/2022, South Central – Oxford C Research Ethics Committee (Health Research Authority, Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 104 8226; oxfordc.rec@hra.nhs.uk), ref: 22/SC/0186

2. approved 19/10/2023, Scotland A Research Ethics Committee (2nd Floor , Waverley Gate 2, 4 Waterloo Place, Edinburgh, EH13EG, United Kingdom; +44 (0)131 465 5680; Manx.Neill@nhslothian.scot.nhs.uk), ref: 23/SS/0082

3. approved 14/05/2024, Nepean Blue Mountains Local Health District HREC (Level 5, Block D (South Block), Nepean Hospital, Penrith, 2751, Australia; +61 (02) 4734 3441; NBMLHD-Ethics@health.nsw.gov.au), ref: 2024/ETH00464

Study design
Randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Critical care

Interventions
Current interventions as of 10/06/2025:
T4P is a large-scale, multi-centre, data-enabled, registry-embedded, open-label, randomised, comparative effectiveness trial with an internal pilot across five equally spaced platelet count thresholds (<10 - <50 x 10e9/L). There will be an integrated economic evaluation.
The trial plans to include 2550 critically ill patients recruited from 66 NHS adult critical care units over a period of 42 months.
The normal platelet count is 150-450 x 10e9/L. Patients whose platelet count is below 50 x 10e9 /L (at any time in their critical care unit stay) and requiring a low bleeding risk invasive procedure will be considered for the trial. Once a patient has been confirmed as eligible (i.e. they satisfy the inclusion and exclusion criteria), they will be randomised (see below) and the randomly allocated treatment commenced as soon as possible.
Prior to an invasive procedure, eligible patients will be randomised to one of five platelet thresholds below which they will receive a single adult equivalent dose (AED) of platelet transfusion for the index procedure and subsequent procedures during their critical care unit stay. The thresholds are:-
1. Platelet count <50 x 10e9/L
2. Platelet count<40 x 10e9/L
3. Platelet count <30 x 10e9/L
4. Platelet count <20 x 10e9/L
5. Platelet count <10 x 10e9/L
Patients will be given a platelet transfusion prior to the invasive procedure if their platelet count is below the threshold to which they have been allocated. Patients remain in their allocated ‘group’ (threshold) for the duration of their critical care unit stay.
In all groups, all other treatments and procedures will be carried out in accordance with standard NHS care and local practice.

CONSENT
As eligible patients will be critically ill at the point in which they become eligible for T4P – a model of research without prior consent (RWPC) (also known as 'deferred consent') is proposed. This model is believed to be the most appropriate as low bleeding risk interventional procedures are often initiated as a life-saving measure, during an emergency clinical situation. Patients will lack mental capacity due to their medical condition and by virtue of serious illness that required admission to a critical care unit (or continuing treatment in critical care) at the point that they become eligible for the trial. Any delay in commencing the trial treatment could be detrimental to the patient, as well as to the scientific validity of the trial.
In brief, once a patient is screened as eligible for the trial (i.e. satisfies inclusion and exclusion criteria), they will be enrolled and randomised to receive the assigned treatment immediately. Patients in critical care units are monitored very closely and clinical/research staff working in this setting have extensive experience of assessing capacity in their patients. For patients recruited in England, Wales and Northern Ireland, once a patient has regained capacity, they will be approached by an authorised member of the site research team for informed deferred consent.

This will be done as soon as practically possible (usually within 24 - 48 hours of the patient regaining capacity). In the interim period - once the patient's medical situation is deemed to no longer be an emergency, a Personal Consultee will be approached (in person or by telephone) to provide their opinion of the patient's wishes regarding participating in the trial. Telephone and postal mechanisms for consent is also in place for the situation where patients are discharged from hospital prior to confirming their consent decision.
This type of consent model is used in clinical trials comparing treatments in emergency clinical situations (such as this one) to find out which is best. The specific model proposed for T4P has been informed/approved by our Patient and Public Involvement (PPI) co-investigator.

For patients recruited in Scotland, consent must be in place prior to randomisation. This can be sought from the patient, or if they lack capacity, from a Personal Legal Representative. If consent sought from a Personal Legal Representative prior to randomisation, consent will then be sought after randomisation from the patient when they regain capacity. This consent model in Scotland has been reviewed and approved by Scotland A REC and is in accordance with the Adults with Incapacity (Scotland) Act 2000.

For patients recruited in the Republic of Ireland, once a patient has regained capacity, they will be approached for consent to continue. In the interim, a substitute decision maker (e.g., family, friend) will be approached for deferred assent.

For patients recruited in Australia, a waiver of consent for enrolment has been granted. Dependent on local jurisdictional requirements and legislation, consent for follow up at 90 days and 12 months will employ either an opt-out or a consent to continue approach. For participating sites using the opt-out approach, the patient, or if they lack capacity and in the interim, person responsible, will be provided with a brochure which will explain the trial and the procedure to decline or opt-out from follow-up. For participating sites using the consent to continue approach, the patient, or if they lack capacity and in the interim, person responsible, will be provided with an information sheet and the opportunity to provide consent.

At 90 days and 1 year, participants will be posted questionnaires about health-related quality of life and their use of health services since leaving hospital. These questionnaires have been used in previous critical care unit trials and will provide valuable information for the integrated economic evaluation. The questionnaires are designed to take no longer than 15 minutes to complete. A stamped addressed envelope and a pen will be included, so it will not cost the patient anything. A trained member of the T4P team at the ICNARC CTU will telephone participants who have not returned the questionnaire after three weeks, to check if they have received it and offer the option of resending the questionnaire (either by post or email) or going through the questionnaire over the telephone. Patient follow-up questionnaires will be administered by the participating site teams in the Republic of Ireland and Australia.

INTERNAL PILOT
The pilot phase will cover the first 12 months of recruitment, assessing recruitment, willingness to randomise, protocol adherence and data quality. Data will be analysed at the end of the internal pilot trial stage. The analysis will take place in month 20 of the trial to allow data to be collected and entered to assess all progression criteria. The outcome of this analysis will be presented to the majority-independent Trial Steering Committee who will provide their recommendation as to whether the trial should continue to the Funder (National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme). The final decision on progression from the pilot stage to the full trial will be made by the NIHR HTA programme after recommendation by the TSC.

INDEPENDENT COMMITTEES
Both a Trial Steering Committee and an independent Data Monitoring & Ethics Committee (DMEC) will be convened and will meet regularly during the trial. The DMEC will monitor recruitment and retention, protocol adherence (including adherence to treatment protocols) and patient safety (including serious adverse events), and will review the interim analysis.

TIMELINE
Months 1-6: Study set-up: all approvals & preparation for the start of the trial (site sign-up and local approvals, production of materials for participating sites, conduct site initiation meetings)
Months 7-48 : Recruitment/follow-up period
Months 7-18: Internal pilot stage
Month 16: First annual REC report
Month 19: First follow-up questionnaires sent
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Month 48: Close to recruitment
Month 52: Final follow-up questionnaires
Months 48-60: Analysis and dissemination
Month 53: Database lock for primary analysis (clinical and economic evaluation) Commence primary analysis and write up
Month 55: Lock database for longer-term outcomes
Month 59: Submit primary outcome paper Collaborators' meeting Final DMEC and TSC meetings
Month 60: Submit longer-term outcomes paper and draft final report to NIHR

Previous interventions as of 07/06/2024:
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Intervention Type
Other

Primary outcome(s)
All-cause mortality at 90 days measured through review of patient medical notes at 90 days post-randomisation and/or data linkage with nationally held death registrations.

Primary health economic outcome measure:
Incremental costs, quality-adjusted life year (QALYs) and net monetary benefit at 90 days, measured through combining Health-related Quality of Life (EuroQol EQ-5D-5L questionnaire) data, valued resource use data obtained via a health services questionnaire and data obtained through linkage with national hospital episode statistics, death registrations and the national clinical audit for adult critical care.

Key secondary outcome(s))
1. Mortality at discharge from critical care unit, hospital and at 1 year, measured through review of patient medical notes at the relevant timepoints and/or data linkage with nationally held death registrations and the national clinical audit for adult critical care (for mortality at discharge)
2. Survival to longest available follow-up, measured by review of patient medical notes and/or data linkage with nationally held death registrations
3. Rates of major and fatal bleeds classified according to the HEmorhage Measurement (HEME) bleeding score, measured through review of patient medical notes up until critical care unit discharge
4. Venous and arterial thromboses in hospital and to 1 year, measured through review of patient medical notes at hospital discharge, data obtained via a health services questionnaire and through data linkage with national hospital episodes statistics and the NICE-mandated hospital-acquired venous thromboembolism (VTE) audit
5. Duration of renal, advanced cardiovascular and advanced respiratory support according to UK Critical Care Minimum Data Set (CCMDS) criteria, measured through review of patient medical notes during critical care admission and data obtained through linkage with the national clinical audit for adult critical care
6. Length of critical care unit and acute hospital stay, measured through review of patient medical notes and data obtained through linkage with the national clinical audit for adult critical care
7. Health-related quality of life measured through EQ-5D-5L questionnaire at 90 days and 1-year

timepoints
8. Resource use and costs at 90 days and 1 year, measured by valuing resource use data obtained via a health services questionnaire administered to patients and through data linkage with national hospital episode statistics and the national clinical audit for adult critical care
9. Net monetary benefit (NMB) at 1 year, measured through combining health-related quality of life (EQ-5D-5L questionnaire) data, valued resource use data obtained via a health services questionnaire and data obtained through linkage with national hospital episode statistics, death registrations and the national clinical audit for adult critical care

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 17/03/2023:
1. Adult (aged 18 years or older)
2. Accepted for admission or admitted to a participating critical care unit
3. Platelet count <50 x 10e9/l
4. Planned to undergo a specified* low bleeding risk invasive procedure OR platelet transfusion being considered for an 'other' procedure

*Specified low bleeding risk invasive procedures include the following:
1. Central venous vascular catheter insertion (including vascular access for renal replacement therapy)
2. Paracentesis/superficial abdominal fluid collection drainage
3. Pleural aspiration

'Other' procedures may be included if the clinician deems these to be a low bleeding risk invasive procedure and a platelet transfusion is being considered for the procedure. These include, but are not limited to, the following:
1. Arterial catheter insertion
2. Arterial or central venous catheter removal
3. Pleural drain
4. Interventional radiology (as defined by Society of Interventional Radiology guidelines)
5. Bronchoscopy with or without lavage
6. Wound dressing changes
7. Surgical procedures where the clinical team agree the risk of bleeding is low, e.g. re-look laparotomy, or wound closure

Previous participant inclusion criteria:
1. Adult (aged 18 years or older)
2. Accepted for admission or admitted to a participating critical care unit
3. Platelet count <50 x 10e9/l
4. Platelet transfusion being considered for a low bleeding risk invasive procedure*

*Low bleeding risk invasive procedures include the following:
1. Vascular catheter insertion and removal (central venous – including vascular access for renal replacement therapy)
2. Paracentesis/superficial abdominal fluid collection drainage
3. Pleural aspiration

‘Other’ procedures may be included if the clinician deems these to be a low bleeding risk invasive procedure. These include, but are not limited to, the following:
1. Arterial catheter line insertion
2. Pleural drain
3. Interventional radiology (as defined by Society of Interventional Radiology guidelines)
4. Bronchoscopy with or without lavage
5. Wound dressing changes
6. Surgical procedures where the clinical team agree risk of bleeding is low, e.g. re-look laparotomy, or wound closure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current participant exclusion criteria as of 17/03/2023:
1. Ongoing major haemorrhage requiring blood products and/or surgical/radiological intervention*
2. Intercranial haemorrhage within prior 72 hours*
3. Contra-indication to platelet transfusion (such as thrombotic microangiopathies; heparin-induced thrombocytopaenia; immune thrombocytopaenia; congenital platelet function defects)
4. Acute promyelocytic leukaemia (APML)
5. Known advance decision refusing blood/blood component transfusions (e.g. Jehovah’s Witnesses)
6. Death perceived as imminent or admission for palliation
7. Previously randomised into T4P
8. Fulfilled all the inclusion criteria and none of the other exclusion criteria ≥72 hours

*Exclusion criteria no. 1 and 2 are dynamic, and if resolved, the patient may be reconsidered for the trial

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Date of first enrolment
19/10/2022

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Ireland

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
England
EN5 3DJ

Study participating centre
Victoria Hospital (blackpool)
Whinney Heys Road
Blackpool
England
FY3 8NR

Study participating centre
Chelsea & Westminster Hospital
369 Fulham Road
London
England
SW10 9NH

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
England
S44 5BL

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
England
CH2 1UL

Study participating centre
Croydon University Hospital
London Road
Croydon
England
CR7 7YE

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre

Great Western Hospital
Marlborough Road
Swindon
England
SN3 6BB

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
England
SE1 9RT

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
England
B9 5ST

Study participating centre
Good Hope Hospital
Rectory Road
Sutton Coldfield
England
B75 7RR

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
John Radcliffe Hospital
Headley Way
Headington

Oxford
England
OX3 9DU

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
England
NN16 8UZ

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

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
England
NG17 4JL

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Liverpool Heart & Chest Hospital
Broadgreen Hospital
Thomas Drive
Liverpool
England
L14 3PE

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
England
NE23 6NZ

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston
England
PE21 9QS

Study participating centre
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham
England
B15 2TH

Study participating centre

Queen Elizabeth Hospital
Woolwich Stadium Road
Woolwich
London
England
SE18 4QH

Study participating centre
Burton Hospital
Queens Hospital
Belvedere Road
Burton-on-trent
England
DE13 0RB

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester

England
SO22 5DG

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
England
L7 8XP

Study participating centre
Royal Papworth Hospital
Papworth Road
Cambridge Biomedical Campus
Cambridge
England
CB2 0AY

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
England
DY1 2HQ

Study participating centre
St Georges at Mayday University Hospital
530 London Road
Thornton Heath
England
CR7 7YE

Study participating centre
St Richards Hospital
Spitalfield Lane
Chichester
England
PO19 6SE

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-lyne
England
OL6 9RW

Study participating centre
Treliske Hospital
Treliske
Truro
England
TR1 3LJ

Study participating centre
University Hospital Coventry
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
Warrington Hospital (site)
Warrington Hospital
Lovely Lane
Warrington
England
WA5 1QG

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth

England
TW7 6AF

Study participating centre
Wexham Park Hospital
Wexham Street
Wexham
Slough
England
SL2 4HL

Study participating centre
The Whittington Hospital
Highgate Hill
London
England
N19 5NF

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
Scotland
AB25 2ZN

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Study participating centre
University Hospital of North Durham
University Hospital of Durham
Dryburn Hospital
North Road
Durham
England
DH1 5TW

Study participating centre
Darlington Memorial Hospital NHS Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre
West Cumbria Health Care NHS Trust
West Cumberland Hospital
Hensingham
Whitehaven
England
CA28 8JG

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

Study participating centre
Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
England
BL9 7TD

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
England
ME7 5NY

Study participating centre
Newham University Hospital NHS Trust
Newham General Hospital
Glen Road
London
England
E13 8SL

Study participating centre
Sir Charles Gairdner Hospital
Hospital Avenue, Nedlands
Perth
Australia
6009

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131822

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from T4P@icnarc.org

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	25/11/2022	22/05/2023	No	No
Protocol file	version 3.1	16/01/2024	07/06/2024	No	No
Protocol file	Australian sites version 1.0	15/04/2024	10/06/2025	No	No
Protocol file	version 4.0	30/06/2025	20/04/2026	No	No
Statistical Analysis Plan	version 1.0		20/04/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes