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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

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| **Submission date**<br>01/09/2022 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>30/09/2022 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>10/06/2025 | **Condition category**<br>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

### Study website
https://www.icnarc.org/Our-Research/Studies/Current-Studies/T4P

# 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

### EudraCT/CTIS number
Nil known

### IRAS number
312405

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 53274, IRAS 312405

## 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## 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
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
Month 20: Second DMEC and TSC meetings to review internal pilot analysis Internal pilot report submitted to NIHR HTA
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 measure
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.

## Secondary outcome measures

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

### Overall study start date
01/01/2022

### 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

## Age group
Adult

## Lower age limit
18 Years

## Sex
Both

## Target number of participants

Planned Sample Size: 2550; UK Sample Size: 2050; International Sample Size: 500

### 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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4. Advance decision refusing blood/blood component transfusions (e.g. Jehovah's Witnesses)
5. Death perceived as imminent or admission for palliation
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7. 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

### Date of first enrolment
19/10/2022

### Date of final enrolment
31/12/2026

## Locations

### Countries of recruitment
Australia

England

Ireland

Northern Ireland

Scotland

United Kingdom

Wales

**Study participating centre**
**Barnet Hospital**
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

**Study participating centre**
**Victoria Hospital (blackpool)**
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

**Study participating centre**
**Chelsea & Westminster Hospital**
369 Fulham Road
London
United Kingdom
SW10 9NH

**Study participating centre**
**Chesterfield Royal Hospital**
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

**Study participating centre**
**Countess of Chester Hospital**
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

**Study participating centre**
**Croydon University Hospital**
London Road
Croydon
United Kingdom
CR7 7YE

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

**Study participating centre**
**Great Western Hospital**
Marlborough Road
Swindon
United Kingdom
SN3 6BB

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

**Study participating centre**
**Heartlands Hospital**
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5ST

**Study participating centre**
**Good Hope Hospital**
Rectory Road
Sutton Coldfield
United Kingdom
B75 7RR

**Study participating centre**
**Hull Royal Infirmary**
Anlaby Road
Hull
United Kingdom
HU3 2JZ

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

**Study participating centre**
**Kettering General Hospital**
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

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

**Study participating centre**
**Kings Mill Hospital**
Mansfield Road

Sutton-in-ashfield
United Kingdom
NG17 4JL

**Study participating centre**
**Leicester Royal Infirmary**
Infirmary Square
Leicester
United Kingdom
LE1 5WW

**Study participating centre**
**Liverpool Heart & Chest Hospital**
Broadgreen Hospital
Thomas Drive
Liverpool
United Kingdom
L14 3PE

**Study participating centre**
**Milton Keynes University Hospital**
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

**Study participating centre**
**Northumbria Specialist Emergency Care Hospital**
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

**Study participating centre**
**Pilgrim Hospital**
Sibsey Road
Boston
United Kingdom
PE21 9QS

**Study participating centre**
**Poole Hospital**
Longfleet Road
Poole
United Kingdom
BH15 2JB

**Study participating centre**
**University Hospital Birmingham**
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

**Study participating centre**
**Queen Elizabeth Hospital**
Woolwich Stadium Road
Woolwich
London
United Kingdom
SE18 4QH

**Study participating centre**
**Burton Hospital**
Queens Hospital
Belvedere Road
Burton-on-trent
United Kingdom
DE13 0RB

**Study participating centre**
**Queens Medical Centre**
Derby Road
Nottingham
United Kingdom
NG7 2UH

**Study participating centre**

**Nottingham City Hospital**
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

**Study participating centre**
**Royal Berkshire Hospital**
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

**Study participating centre**
**Royal Hampshire County Hospital**
Romsey Road
Winchester
United Kingdom
SO22 5DG

**Study participating centre**
**Royal Liverpool University Hospital**
Prescot Street
Liverpool
United Kingdom
L7 8XP

**Study participating centre**
**Royal Papworth Hospital**
Papworth Road
Cambridge Biomedical Campus
Cambridge
United Kingdom
CB2 0AY

**Study participating centre**
**New Cross Hospital Royal Wolverhampton**
Wolverhampton Road
Heath Town
Wolverhampton

United Kingdom
WV10 0QP

**Study participating centre**
**Russells Hall Hospital**
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

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

**Study participating centre**
**St Richards Hospital**
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

**Study participating centre**
**Tameside General Hospital**
Fountain Street
Ashton-under-lyne
United Kingdom
OL6 9RW

**Study participating centre**
**Treliske Hospital**
Treliske
Truro
United Kingdom
TR1 3LJ

**Study participating centre**

**University Hospital Coventry**
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

**Study participating centre**
**Warrington Hospital (site)**
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

**Study participating centre**
**West Middlesex University Hospital**
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

**Study participating centre**
**Wexham Park Hospital**
Wexham Street
Wexham
Slough
United Kingdom
SL2 4HL

**Study participating centre**
**The Whittington Hospital**
Highgate Hill
London
United Kingdom
N19 5NF

**Study participating centre**
**Aberdeen Royal Infirmary**
Foresterhill Road

Aberdeen
United Kingdom
AB25 2ZN

**Study participating centre**
**Western General Hospital**
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

**Study participating centre**
**University Hospital of North Durham**
University Hospital of Durham
Dryburn Hospital
North Road
Durham
United Kingdom
DH1 5TW

**Study participating centre**
**Darlington Memorial Hospital NHS Trust**
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

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

**Study participating centre**
**Salford Royal Hospital**
Stott Lane
Eccles

Salford
United Kingdom
M6 8HD

**Study participating centre**
**Fairfield General Hospital**
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

**Study participating centre**
**Medway NHS Foundation Trust**
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

**Study participating centre**
**Newham University Hospital NHS Trust**
Newham General Hospital
Glen Road
London
United Kingdom
E13 8SL

**Study participating centre**
**St Vincent's University Hospital**
Elm Park
Dublin 4
Dublin
Ireland
D04 T6F4

**Study participating centre**
**Royal Brisbane and Women's Hospital**
-

Brisbane
Australia
4029

**Study participating centre**
**Cairns Hospital**
Cairns
Australia
4870

**Study participating centre**
**Gold Coast University Hospital**
Gold Coast
Australia
4215

**Study participating centre**
**Mater Misericordiae Ltd**
Newstead
Australia
4006

**Study participating centre**
**Toowoomba Hospital**
Toowoomba
Australia
4350

**Study participating centre**
**Fiona Stanley Hospital**
Perth
Australia
6150

**Study participating centre**
**Royal Perth Hospital**
Perth
Australia
6000

**Study participating centre**
**Sir Charles Gairdner Hospital**
Perth
United Kingdom
6009

**Study participating centre**
**Bunbury Regional Hospital**
Bunbury
Australia
6230

**Study participating centre**
**The Canberra Hospital**
Canberra
Australia
2605

**Study participating centre**
**Royal North Shore Hospital**
Sydney
Australia
2065

**Study participating centre**
**Campbelltown Hospital**
Sydney
Australia
2560

**Study participating centre**
**Austin Hospital**
Melbourne
Australia
3084

**Study participating centre**
**Royal Melbourne Hospital**
Melbourne
Australia
3050

**Study participating centre**
**St Vincent's Hospital**
Melbourne
Australia
3065

**Study participating centre**
**Ballarat Hospital**
Ballarat
Australia
3350

**Study participating centre**
**Footscray Hospital**
Footscray
Australia
3011

**Study participating centre**
**Sunshine Hospital**
St Albans
Australia
3021

**Study participating centre**
**Monash Medical Centre**
Melbourne
Australia
3021

**Study participating centre**
**Victorian Heart Hospital**
Clayton

Australia
3168

**Study participating centre**
**The Alfred**
Melbourne
Australia
3004

**Study participating centre**
**St Vincent's Hospital**
Sydney
Australia
2010

**Study participating centre**
**Blacktown Hospital**
Blacktown
Australia
2148

# Sponsor information

**Organisation**
University of Oxford

**Sponsor details**
Research Governance, Ethics and Assurance
Joint Research Office
Boundary Brook House
Churchill Drive
Headington
Oxford
United Kingdom
OX3 7GB
+44 (0)1865 289884
ctrg@admin.ox.ac.uk

**Sponsor type**
University/education

**Website**
http://www.ox.ac.uk/

**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

**Publication and dissemination plan**
The results of T4P will be disseminated actively and extensively. This will cover both progress during the trial period and the results at the end of the study. Outputs will include, but will not be limited to, the following areas:
1. Meeting and conference presentations (international and national) of study progress and results
2. Publication of study (1) protocol, (2) statistical analysis plan, (3) primary results, and (4) longer-term outcomes, including economic evaluation

**Intention to publish date**
31/12/2028

**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**
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 2.0 | 25/11/2022 | 22/05/2023 | No | No |
| HRA research summary | | | 28/06/2023 | 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 |