

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

<b>Submission date</b> 01/09/2022	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/06/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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  $50 \times 10^9/L$  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**

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### **Type(s)**

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### **Contact name**

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## **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 ( $<10$  -  $<50 \times 10^9/L$ ). 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  $150-450 \times 10^9/L$ . Patients whose platelet count is below  $50 \times 10^9/L$  (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  $<50 \times 10^9/L$
2. Platelet count  $<40 \times 10^9/L$
3. Platelet count  $<30 \times 10^9/L$
4. Platelet count  $<20 \times 10^9/L$
5. Platelet count  $<10 \times 10^9/L$

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

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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 HEmorrhage 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  $<50 \times 10^9/l$
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  $<50 \times 10^9/l$

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. Intracranial haemorrhage within prior 72 hours\*
3. Contra-indication to platelet transfusion (such as thrombotic microangiopathies; heparin-induced thrombocytopenia; immune thrombocytopenia; 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  $\geq 72$  hours

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

Previous participant exclusion criteria:

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2. Intracranial haemorrhage within prior 72 hours\*
3. Contra-indication to platelet transfusion (such as thrombotic microangiopathies; heparin-induced thrombocytopenia; immune thrombocytopenia; congenital platelet function defects)
4. Advance decision refusing blood/blood component transfusions (e.g. Jehovah's Witnesses)
5. Death perceived as imminent or admission for palliation
6. Previously randomised into T4P
7. Fulfilled all the inclusion criteria and none of the other exclusion criteria  $\geq 72$  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  
ctrq@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?
<a href="#">Protocol file</a>	version 2.0	25/11/2022	22/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 3.1	16/01/2024	07/06/2024	No	No
<a href="#">Protocol file</a>	Australian sites version 1.0	15/04/2024	10/06/2025	No	No