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# A national perioperative platform trial to improve outcomes for surgical patients (PROTECT)

**Submission date**
20/06/2025

**Recruitment status**
Recruiting

**Registration date**
23/06/2025

**Overall study status**
Ongoing

**Last Edited**
13/03/2026

**Condition category**
Surgery

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

## Plain English summary of protocol

Background and study aims
Clinical implementation of new treatments requires evidence from clinical trials. Traditional clinical trials compare two groups: a treatment group and a control group. However, traditional trials are time-consuming and expensive, often taking a long time to set-up, open new centres and start enrolling patients. This delays implementation of new treatments. Platform trials offer a new approach that was used very successfully during the pandemic. Instead of comparing one treatment group to one control group, platform trials compare multiple treatment groups to one control group. Once established, platforms continue to run, with new treatments added as they become available. This reduces the overall number of patients required and reduces the time and cost of setting up a new trial, which makes platform trials a very efficient way to test new treatments. Our aim is to establish a national platform trial for surgical patients is urgently needed.

Who can participate?
Patients aged 18 years and over being treated in a surgical care pathway.

What does the study involve?
This is a trial designed to test multiple research questions for patients undergoing surgery, or within a surgical care pathway. Patient eligibility will be evaluated separately for each research question and they will be offered the opportunity to take part in any or all of the studies for which they are eligible.

For participants who enrol in the PROTECT platform only, a common outcome dataset will be collected at 30 days and 90 days after surgery about their health and well-being. In addition, longer-term outcomes may be collected using national NHS databases including Hospital Episode Statistics or the equivalent databases in Wales, Scotland and Northern Ireland, and Civil Registration Data.

What are the possible benefits and risks of participating?
Participants may not benefit directly from taking part in this study. By taking part in studies

looking at new ways to improve the care they will receive and by allowing the research team to collect information about their healthcare, we hope to improve the health outcomes for surgical patients in the future.

Where is the study run from?
Surgical services of participating hospitals (UK)

When is the study starting and how long is it expected to run for?
March 2026 to February 2035

Who is funding the study?
1. Bart's Charity (G-002514)
2. Academy of Medical Science (SGL029\1104)
3. British Journal of Anaesthesia (WKR0-2023-0016)

Who is the main contact?
1. Priyanthi Dias (p.dias@qmul.ac.uk)
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# Contact information

### Type(s)
Public

### Contact name
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### Type(s)
Scientific, Principal investigator

### Contact name
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### ORCID ID
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
353122

### Protocol serial number
Nil known

# Study information

### Scientific Title
A national perioperative platform trial to improve outcomes for surgical patients (PROTECT)

### Acronym
PROTECT

### Study objectives
To establish a research and governance infrastructure for the efficient delivery of a suite of surgical and/or perioperative care comparisons to improve outcomes for patients undergoing surgery.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 03/02/2025, London - South East Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8222; londonsoutheast.rec@hra.nhs.uk), ref: 25/LO/0043

### Study design
This is a multi-centre multi-factorial platform trial designed to test multiple comparisons (research questions) for patients undergoing surgery, or within a surgical care pathway. Patient eligibility will be evaluated for the platform (master protocol) and for each comparison (protocol appendix). Patients enrolled in the PROTECT platform will be offered the opportunity to take part in any and/or all of the comparisons for which they are eligible. Patients can be enrolled in the platform (master protocol) only or the platform (master protocol) plus one or more comparison(s). Comparisons may be contemporaneous or distributed throughout the surgical

care pathway. As new comparisons are added to the platform, they will be assigned a comparison-specific acronym suffix (e.g. PROTECT-AEGIS, etc.), and the comparison-specific trial methodology and delivery will be described in separate appendices to this master protocol document. Each comparison will be added as an individual submission to the relevant regulatory authorities. Amendments made to the master protocol will apply to all appendices. Amendments to an appendix describing an individual comparison(s) will only be relevant to that appendix.

The PROTECT master protocol is the over-arching protocol which describes the common trial design, delivery and data sets, as well as trial governance procedures common to all comparisons within the platform. Where additional procedures are required, specific to a comparison, for example the collection of additional safety data, these will be described in the appendix for that comparison. The individual appendices are not co-dependent and each will have a separate start and end date. Appendices to the PROTECT master protocol will be added and/or removed throughout the course of the programme. Analyses will be conducted on locked comparison specific datasets and published without compromising the integrity of ongoing platform comparisons. Each individual comparison will have a lead investigator listed in the comparison appendix. Participants enrolled into PROTECT will fall into one or more of the below study categories depending on the eligibility criteria and the journey of their care pathway:
• PROTECT platform
• Non-interventional (non-randomised) studies
• Interventional studies that do not involve Investigational Medicinal Products (IMPs)
• Interventional studies that involve an IMP

## Primary study design
Interventional

## Study type(s)
Efficacy, Quality of life, Treatment

## Health condition(s) or problem(s) studied
All adult patients (≥18 years) being treated within a surgical care pathway at the recruitment sites will be eligible for the trial.

## Interventions
A common outcome dataset will be collected for all patients at 30 days and 90 days after surgery. In addition, longer-term outcomes may be collected using routinely collected data (for example Hospital Episode Statistics (HES) and Civil Registration data) up until the last follow up time-point for the participant according to the nature of the groups in which they are enrolled in. Where applicable, primary and secondary outcomes will be described in full in the relevant appendix. Additionally, for CTIMPs, depending on the risk and status of the investigations, part of the objectives will be to collect safety endpoints.

## Intervention Type
Other

## Primary outcome(s)
Current primary outcome(s) as of 12/01/2026:
1. Mortality at 1 year after surgery.
2. Longitudinal mortality, complications and health resource use until the closure of the PROTECT platform.

3. Complications within 30 days after surgery
4. Days alive and at home at 30 and 90 days after surgery
5. Mortality at 30 and 90 days and one year after surgery
6. Health-related quality of Life (EQ-5D-5L) at 30 and 90 days after surgery
7. Duration of primary hospital admission up to 90 days after surgery
8. Re-admission to hospital within 90 days of surgery

Previous primary outcome(s):
Measured using patient records:
1. Complications within 30 days after surgery
2. Days alive and at home at 30 and 90 days after surgery
3. Mortality at 30 and 90 days and 1 year after surgery
4. Health-related quality of Life (EQ-5D-5L) at 30 and 90 days after surgery
5. Duration of primary hospital admission up to 90 days after surgery
6. Re-admission to hospital within 90 days of surgery

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
01/02/2035

## Eligibility

### Key inclusion criteria
All adult patients (≥18 years) being treated within a surgical care pathway at the recruitment sites will be eligible for the trial.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria

Inability or refusal to provide informed consent.

### Date of first enrolment
06/03/2026

### Date of final enrolment
01/01/2035

## Locations

### Countries of recruitment
United Kingdom

England

Scotland

Wales

### Study participating centre
**Barts Health NHS Trust**
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

### Study participating centre
**Plymouth Hospitals NHS Trust**
Derriford Hospital
Derriford Road
Crownhill
Plymouth
England
PL6 8DH

### Study participating centre
**The Royal Marsden Hospital**
Fulham Road
London
England
SW3 6JJ

**Study participating centre**
**University Hospitals Birmingham NHS Foundation Trust**
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

**Study participating centre**
**University Hospital Southampton NHS Foundation Trust**
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

**Study participating centre**
**Croydon Health Services NHS Trust**
Croydon University Hospital
530 London Road
Thornton Heath
England
CR7 7YE

**Study participating centre**
**The Newcastle upon Tyne Hospitals NHS Foundation Trust**
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

**Study participating centre**
**Leeds Teaching Hospitals NHS Trust**
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

**Study participating centre**
**Barking, Havering and Redbridge University Hospitals NHS Trust**
Queens Hospital
Rom Valley Way
Romford
England
RM7 0AG

**Study participating centre**
**NHS National Waiting Times Centre Board**
Agamemnon Street
Clydebank
Scotland
G81 4DY

**Study participating centre**
**NHS Grampian**
Summerfield House
2 Eday Road
Aberdeen
Scotland
AB15 6RE

**Study participating centre**
**Surrey and Sussex Healthcare NHS Trust**
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

**Study participating centre**
**Manchester University NHS Foundation Trust**
Cobbett House
Oxford Road
Manchester
England
M13 9WL

**Study participating centre**
**South Tyneside and Sunderland NHS Foundation Trust**
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

**Study participating centre**
**Cardiff and Vale University Health Board**
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

**Study participating centre**
**North Bristol NHS Foundation Trust**
Southmead Hospital
Southmead Road
Bristol
England
BS10 5NB

**Study participating centre**
**Liverpool University Hospitals NHS Foundation Trust**
Mount Vernon Street
Liverpool
England
L7 8YE

**Study participating centre**
**Royal Surrey NHS Foundation Trust**
Royal Surrey County Hospital
Egerton Road
Guildford
England
GU2 7XX

**Study participating centre**

**York and Scarborough Teaching Hospitals NHS Foundation Trust**
York Hospital
Wigginton Road
York
England
YO31 8HE

**Study participating centre**
**The Dudley Group NHS Foundation Trust**
Russells Hall Hospital
Pensnett Road
Dudley
England
DY1 2HQ

# Sponsor information

**Organisation**
Queen Mary University of London

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Charity

**Funder Name**
Barts Charity

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

**Funder Name**
British Journal of Anaesthesia

**Alternative Name(s)**
British Journal of Anaesthesia Ltd, BJA

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

**Funder Name**
Academy of Medical Sciences

**Alternative Name(s)**
The Academy of Medical Sciences

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
Available on request. Data sharing statement to be made available at a later date.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 2.0 | 19/06/2025 | 17/12/2025 | No | Yes |
| Protocol file | version 3.0 | 19/06/2025 | 17/12/2025 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |