

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

Submission date 20/06/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/03/2026	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

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Contact information

Type(s)

Public

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Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)

353122

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