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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
23/06/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] 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 an NHS 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 NHS hospitals (UK)

When is the study starting and how long is it expected to run for?
January 2025 to December 2034

Who is funding the study?
1. Barts 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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Study website
https://www.protectresearch.org

Contact information

Type(s)
Public

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Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
353122

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Platform trial

Study setting(s)
Hospital

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

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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 one 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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2025

Completion date
01/01/2035

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
932

Key exclusion criteria
Inability or refusal to provide informed consent.

Date of first enrolment
01/01/2025

Date of final enrolment
01/01/2035

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Plymouth Hospitals NHS Trust
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
The Royal Marsden Hospital
Fulham Road
London

United Kingdom
SW3 6JJ

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

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

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

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

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street

Leeds
United Kingdom
LS9 7TF

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

Study participating centre
NHS National Waiting Times Centre Board
Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

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

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester

United Kingdom
M13 9WL

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

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Sponsor information

Organisation
Queen Mary University of London

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Joint Research Management Office
Dept W, 69-89 Mile End Road
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Sponsor type
University/education

Website
https://www.jrmo.org.uk/

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

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data arising from this research will be made available to the scientific community in a timely and responsible manner. Detailed scientific reports will be submitted to a widely accessible scientific journal on behalf of the PROTECT Group. The PSC will agree the membership of a writing committee, which will take primary responsibility for final data analysis and writing of the scientific report(s). All members of the writing committee will comply with internationally agreed requirements for authorship and will approve the final manuscript prior to submission.

The full study report will be accessible via ISRCTN or other suitable public registry within one year of the End of the Trial Notification. Please see PROTECT publication charter for further details.

Intention to publish date

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