

Improving diversity in clinical research for patients undergoing surgery (PROTECT-DIVERSITY)

Submission date 26/11/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/12/2025	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

The lack of diversity in clinical trials is an important issue, which limits external validity. We are doing this study to check whether consent forms in several different languages can improve access to research for patients having surgery. We will also compare the accuracy and completeness of diversity data collection using different methods such as in your medical records, as part of questionnaires and by asking participants questions.

Who can participate?

Adults aged 18 years and over undergoing elective surgery.

What does the study involve?

Patients will be asked to consent to be part of the PROTECT Trial. The consent materials will either be in a traditional paper format or an electronic format, assigned at random. Information such as sex, ethnicity, partnership status, disability, pregnancy status, religion, sexual orientation, gender and gender identity will be collected as part of the PROTECT trial, and patients can refuse to answer any questions they do not want to.

What are the possible benefits and risks of participating?

The information collected may improve how we collect diversity information for patients taking part in clinical trials in the future. There are no disadvantages to taking part in this study.

Where is the study run from?

Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?

The study is starting in December 2025 and will run for 2 years.

Who is funding the study?

The British Journal of Anaesthesia and the Academy of Medical Sciences

Who is the main contact?
Dr Tom Abbott, protect-admin@qmul.ac.uk

Contact information

Type(s)

Scientific, Public, Principal investigator

Contact name

Dr Tom Abbot

Contact details

Royal London Hospital
London
United Kingdom
E1 1FR
+44 203 594 0348
t.abbott@qmul.ac.uk

Additional identifiers

Central Portfolio Management System (CPMS)

65329

Grant Code

WKRO-2023-0016

Integrated Research Application System (IRAS)

350756

Study information

Scientific Title

Diversity in perioperative research

Acronym

PROTECT-DIVERSITY

Study objectives

1. Compare the impact of using multi-lingual consent forms with consent forms in English on the ethnic diversity of patients included in the study.
2. Compare the accuracy and completeness of protected characteristics data collection using different methods.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 10/02/2025, London – South East Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8222; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0887

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Single

Purpose

Health services research

Study type(s)

Health condition(s) or problem(s) studied

Adult patients undergoing elective surgery

Interventions

The master protocol is registered at <https://www.isrctn.com/ISRCTN14639555>

The method of informed consent will use either an electronic or paper method, which is consistent with the master protocol. For this comparison, the mode of consent (electronic or paper) will be determined at random before approaching the patient, which includes consent for entry into the platform. Since the intervention in question is the process of consent, it will not be possible to obtain consent before the 'intervention' i.e. the consent process. In this case, there will be a waiver of consent to randomise to intervention or usual care (electronic consent or paper consent). After randomisation, the patient will complete the consent process using either electronic multi-lingual consent documents or paper consent documents in English, according to group allocation. This process supersedes the procedure for timing of informed consent detailed in the master protocol section nine, which will apply to consent for inclusion in the platform (master protocol) and this comparison. Electronic consent materials will be translated into Polish, Romania, Panjabi, Urdu and Portuguese, which are the five most common languages for people where English/Welsh is not their first language. Translations will be undertaken by an approved/certified provider

Intervention Type

Other

Primary outcome(s)

Reciprocal diversity index for ethnicity on a scale of 0 to 100 at end of trial

Key secondary outcome(s)

1. Completeness of data collection for protected characteristics at trial end
2. Degree of agreement for protected characteristics data between data collection modalities at trial end

Completion date

01/02/2027

Eligibility

Key inclusion criteria

1. Patients aged 18 years and over undergoing elective surgery

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

1. Inability to provide informed consent
2. Co-enrolment in PROTECT CTIMP comparisons
3. Previous enrolment to the PROTECT-DIVERSITY comparison

Date of first enrolment

06/03/2026

Date of final enrolment

01/01/2027

Locations

Countries of recruitment

United Kingdom

England

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

Sponsor information

Organisation
Queen Mary University of London

ROR
<https://ror.org/026zzn846>

Funder(s)

Funder type
Government

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**IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Consent form	19/06/2025	01/12/2025	No	No
Protocol file	version 3.0	19/06/2025	01/12/2025	No	No