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Oxygen treatment using high flow nasal oxygen after major abdominal surgery

Submission date
26/11/2025

Recruitment status
Recruiting

Registration date
03/12/2025

Overall study status
Ongoing

Last Edited
03/12/2025

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
We are studying better ways to look after patients who have surgery. We hope these new techniques will help patients recover more quickly after surgery, so they can return home sooner, and in better health. One approach that may help is to use a device, which assists a patient's breathing immediately after abdominal surgery. We think this may help patients recover better and avoid complications such as chest infection, which can occur in a small number of patients. If we can show that patients and doctors are comfortable taking part in this small trial, we will then perform a much larger clinical trial that will tell us which patients may benefit from the treatment.

Who can participate?
Patients aged 50 years and over, undergoing major abdominal surgery

What does the study involve?
The patient's operation will proceed as planned, and almost all treatment will not change. As they wake up after surgery, they will be either offered extra oxygen through a loose facemask, which is standard treatment, or given treatment to help them breathe more easily. This is called High Flow Nasal Oxygen, or HFNO for short. HFNO provides extra oxygen and is delivered through a nasal cannula device that sites just under the nose. If offered HFNO, this will be for the first four hours after waking up from the operation. If allocated to receive usual treatment of the standard facemask oxygen, no medical care will change. Medical notes will be review until discharge from hospital, up to 30 days.

What are the possible benefits and risks of participating?
Breathing after surgery may be temporarily better if taking part in the study and receive HFNO, but this isn't known for certain. The treatment is very safe and has been used in hospital for many years. All patients will be carefully monitored throughout to ensure any problems are detected and treated promptly. By collecting this information about HFNO and recovery, we hope to work out if HFNO is helpful for patients recovering from surgery and it may help improve care of patients in the future.

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 will start in December 2025 and run for 12 months.

Who is funding the study?
Barts Charity and the British Journal of Anaesthesia.

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

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Tom Abbott

Contact details
Royal London Hospital
London
United Kingdom
E1 1FR
+44 (0)203 594 0349
Protect-admin@qmul.ac.uk

Type(s)
Public

Contact name
Ms Becky Dodds

Contact details
Royal London Hospital
London
United Kingdom
E1 1FR
+44 (0)203 594 0349
Protect-admin@qmul.ac.uk

Additional identifiers

Central Portfolio Management System (CPMS)
65317

Grant Code
WKR0-2023-0016

Integrated Research Application System (IRAS)
350757

Study information

Scientific Title
High flow nasal oxygen for patients undergoing elective major abdominal surgery

Acronym
PROTECT-HFNO

Study objectives
1. To demonstrate willingness of patients to participate in the trial
2. To demonstrate whether relevant healthcare staff within participating hospitals are willing to randomise patients into the trial
3. To provide feasibility data on the clinical effects of HFNO, in reducing postoperative pulmonary complications and days alive and at home (DAH30) after elective major abdominal surgery, compared to standard care
4. To provide safety data on the use of High Flow Nasal Oxygen (HFNO) in patients undergoing elective major abdominal surgery

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 (0)207 104 8222; londonsoutheast.rec@hra.nhs.uk), ref: 24/LO/0888

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult patients undergoing elective major abdominal surgery

Interventions
The master protocol for this study is registered at https://www.isrctn.com/ISRCTN14639555

Eligible patients will be approached for consent before surgery. If consented their baseline and demographic information will be collected for study purposes. There are two groups a patient will be randomly allocated to after surgery, usual care or High Flow Nasal Oxygen (HFNO) administered for 4 hours post surgery, other information pertaining to the surgical procedure and follow up information at 30 days will also be collected to answer the research question.

Intervention Type
Other

Primary outcome(s)
Patient outcome measures:
1. Postoperative pulmonary complications within 30 days after surgery, a composite outcome comprising: pneumonia, Acute Respiratory Distress Syndrome and/or Pulmonary Aspiration.
2. Re-intubation within 30 days after surgery.
3. DAH30
4. All complications graded by Clavien-Dindo within 30 days of surgery
5. Mortality within 30 days of surgery
6. Duration of hospital stay (number of days from day or surgery until hospital discharge) within 30 days after surgery
7. Compliance with HFNO, including duration delivered and any reasons for discontinuation
8. Adverse events associated within HFNO within 12 hours from end of surgery

Hospital level outcome measures:
1. Number of eligible patients per year in each hospital
2. Number of patients consented per year in each hospital
3. Included hospital randomising at least one patient within the 12-month recruitment period
4. Number of consultant surgeons and anaesthetists in each hospital who support recruitment of the patients in their care in principle as a proportion of those delivering care for elective major abdominal surgery
5. Number of consultant surgeons and anaesthetists in each hospital who do not support recruitment of the patients in their care in principle as a proportion of those delivering care for elective major abdominal surgery

Key secondary outcome(s))
There are no secondary outcome measures as this is a feasibility study

Completion date
01/02/2027

Eligibility

Key inclusion criteria
1. Patients aged 50 years and over undergoing elective major abdominal surgery, using open, laparoscopic or robotic surgical technique

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability or refusal to provide informed consent
2. Anticipated requirement for invasive or non-invasive respiratory support for at least 4 hours after surgery as part of routine clinical care
3. Previous enrolment in the PROTECT-HFNO comparison
4. Clinician refusal

Date of first enrolment
01/02/2026

Date of final enrolment
01/12/2026

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
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

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