

# Oxygen treatment using high flow nasal oxygen after major abdominal surgery

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<b>Registration date</b> 03/12/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/12/2025	<b>Condition category</b> 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

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 sits 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 reviewed 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**  
WKRO-2023-0016

## 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](mailto: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 of 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?
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<a href="#">Other files</a>	Consent form	19/06/2025	01/12/2025	No	No
<a href="#">Protocol file</a>	version 3.0	19/06/2025	01/12/2025	No	No