

# Can we reduce the environmental impact of nitrous oxide anaesthesia without affecting patient care?

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<b>Registration date</b> 27/02/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/03/2026	<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

Nitrous oxide is a gas used in anaesthesia. The way it is currently used leads to waste and may have an environmental impact too. The way nitrous oxide is delivered is changing in operating theatres. Currently, most hospitals use piped nitrous oxide, whereas in future nitrous oxide may come from a portable cylinder instead. The aim of this study is to check whether nitrous oxide from portable cylinders is as safe for patients and less wasteful than piped nitrous oxide.

### Who can participate?

All patients undergoing surgery under general anaesthetic

### What does the study involve?

Patients requiring nitrous oxide anaesthesia during their operation will be randomly allocated to receive it either via cylinder or pipeline. No trial-specific data will be collected from the patient, the collection of outcome data will be via hospital record review.

### What are the possible benefits and risks of participating?

There will be no direct benefits to individual patients. The intervention (nitrous oxide delivered via cylinder) is in common clinical practice in the UK, therefore there are no specific risks relating to participation in the trial, however, the purpose of the study is to assess whether there is any difference in the safety profile of nitrous oxide delivered via cylinder or via pipeline.

### Where is the study run from?

The University of Birmingham (UK)

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

February 2024 to March 2027

### Who is funding the study?

The National Institute for Health and Care Research (UK)

Who is the main contact?

Prof. Rupert Pearse, NOBLE@trials.bham.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Mr Rupert Pearse

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Public

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## **Additional identifiers**

**Integrated Research Application System (IRAS)**  
347203

**Central Portfolio Management System (CPMS)**  
63886

**Protocol serial number**  
RG\_24-084

## **Study information**

### **Scientific Title**

A multi-centre non-inferiority cluster trial comparing outcomes related to nitrous oxide delivery by portable cylinder and pipeline in all patients undergoing surgery under general anaesthesia: Nitrous Oxide management to Balance healthcare and Environmental needs (NOBLE)

### **Acronym**

NOBLE

### **Study objectives**

Nitrous oxide delivered via portable cylinder is as safe in terms of patient outcomes as nitrous oxide delivered via pipeline manifold.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 20/02/2025, East of England - Cambridge Central Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8089; cambridgecentral.rec@hra.nhs.uk), ref: 24/EE/0268

### **Study design**

Pragmatic multi-centre non-inferiority cluster randomized cross-over trial

### **Primary study design**

Interventional

### **Study type(s)**

Safety

### **Health condition(s) or problem(s) studied**

Method of nitrous oxide delivery in patients requiring surgery under general anaesthetic.

### **Interventions**

The NOBLE trial will have two distinct phases each lasting 5 weeks. Hospitals will be randomised 1:1 either to a control phase (pipeline nitrous oxide supply) followed by an intervention phase (cylinder nitrous oxide supply), or to an intervention phase followed by a control phase. The total trial intervention period will last 10 weeks, with a further 30 days to complete the follow-up of the last included patient to undergo surgery. Hospitals will be allocated in randomised blocks of random length (4 or 6). The allocation list will be prepared by an independent statistician at BCTU, and uploaded to the randomisation module of the REDCap electronic data capture tools hosted at Birmingham University, to ensure allocation concealment when each hospital is randomised. Prior to randomisation, local investigators will ensure all necessary equipment has been procured and is ready for use and will plan the delivery of education and training to anaesthetists and relevant theatre staff.

## **Intervention Type**

Other

## **Primary outcome(s)**

Days Alive and At Home Within 30 Days after surgery (DAH30). The day of surgery is defined as day zero. Patients who die within 30 days after surgery will be given a value of zero. DAH30 data will be collected from routine data in patient health records by local investigators who are members of the direct care team.

## **Key secondary outcome(s)**

1. Use of nitrous oxide anaesthesia during surgery (Y/N)
2. Mortality within 30 days after surgery
3. Major complications during surgery (Clavien-Dindo grade  $\geq$ III)
4. Duration of hospital stay (days)
5. NHS costs of nitrous oxide provision

All secondary outcome measures will be collected from routine hospital records at 30 days after surgery

## **Completion date**

31/03/2027

# **Eligibility**

## **Key inclusion criteria**

All patients (adults and children) undergoing surgery under general anaesthesia in participating hospitals (regardless of exposure to nitrous oxide anaesthesia)

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

All

## **Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Patients who have opted out of anonymous data sharing

Patients undergoing repeat surgery within 30 days after a procedure recorded in the NOBLE trial

**Date of first enrolment**

01/04/2025

**Date of final enrolment**

31/12/2026

## **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**

**Royal Free London NHS Foundation Trust**

Royal Free Hospital

Pond Street

London

England

NW3 2QG

**Study participating centre**

**University Hospitals Plymouth NHS Trust**

Derriford Hospital

Derriford Road  
Derriford  
Plymouth  
England  
PL6 8DH

**Study participating centre**  
**Mid and South Essex NHS Foundation Trust**  
Nether Mayne  
Basildon  
England  
SS16 5NL

**Study participating centre**  
**County Durham and Darlington NHS Foundation Trust**  
Darlington Memorial Hospital  
Hollyhurst Road  
Darlington  
England  
DL3 6HX

**Study participating centre**  
**Barnet Hospital**  
Wellhouse Lane  
Barnet  
England  
EN5 3DJ

**Study participating centre**  
**Royal Cornwall Hospitals NHS Trust**  
Royal Cornwall Hospital  
Treliske  
Truro  
England  
TR1 3LJ

**Study participating centre**  
**South Tees Hospitals NHS Foundation Trust**  
James Cook University Hospital  
Marton Road  
Middlesbrough

England  
TS4 3BW

**Study participating centre**

**Wye Valley NHS Trust**

County Hospital  
27 Union Walk  
Hereford  
England  
HR1 2ER

**Study participating centre**

**London North West University Healthcare NHS Trust**

Northwick Park Hospital  
Watford Road  
Harrow  
England  
HA1 3UJ

**Study participating centre**

**South Tyneside and Sunderland NHS Foundation Trust**

Sunderland Royal Hospital  
Kayll Road  
Sunderland  
England  
SR4 7TP

**Study participating centre**

**University Hospitals of Derby and Burton NHS Foundation Trust**

Royal Derby Hospital  
Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**

**Burton Hospital**

Queens Hospital  
Belvedere Road

Burton-on-trent  
England  
DE13 0RB

### **Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**  
Royal Victoria Infirmary  
Queen Victoria Road  
Newcastle upon Tyne  
England  
NE1 4LP

## **Sponsor information**

### **Organisation**

University of Birmingham

### **ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Institute for Health and Care Research

### **Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Rachel Lillywhite (NOBLE@trials.bham.ac.uk)

## IPD sharing plan summary

Available on request