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

Submission date
24/10/2024

Recruitment status
Recruiting

Registration date
27/02/2025

Overall study status
Ongoing

Last Edited
17/02/2026

Condition category
Surgery

[X] 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
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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
347203

ClinicalTrials.gov (NCT)
Nil known

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 ≥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