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A study to compare two methods of oxygen delivery during transcatheter aortic valve implantation (TAVI)

Submission date
15/04/2019

Recruitment status
No longer recruiting

Registration date
30/04/2019

Overall study status
Completed

Last Edited
17/04/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This is a study of two different methods of providing oxygen to patients having a transcatheter aortic valve implantation (TAVI) under conscious sedation. TAVI is a type of treatment for patients who have a narrowing of the aortic valve in the heart (aortic stenosis). Traditionally treatment of aortic stenosis has required open-heart surgery but with this procedure doctors can place a new valve in the heart through one of the large blood vessels in the leg (transfemoral TAVI). Usually patients having a TAVI recover from their treatment faster and can go home sooner. Also, unlike patients having open-heart surgery, patients having a TAVI will be under conscious sedation, meaning they will have been given medication to make them relaxed and sleepy but will be awake. Studies have shown that this leads to reduced procedure times, fewer complications and faster recovery. Sometimes during a TAVI the patient's blood oxygen levels can become too low (known as hypoxaemia). Therefore all patients having a TAVI under conscious sedation need to be given oxygen. This study is investigating two different methods of providing oxygen to patients having a TAVI under conscious sedation. These are:
Standard oxygen therapy: patients are given 2 l/min of oxygen via nasal cannula (tube) increasing to 8 l/min if required (which is our normal practice).
High Flow Nasal Oxygen (HFNO): patients are given a high flow nasal oxygen delivery device. Oxygen from this device is heated and humidified, starting with a low flow of 30% oxygen at 30 l /min and slowly increased up to 50l/min if needed.
The two devices are compared to see if either is better at preventing hypoxaemia or leads to improved patient comfort.

Who can participate?
Patients aged over 18 who are scheduled to have a transfemoral TAVI

What does the study involve?
Before the procedure starts participants are randomly allocated to be given one of the two oxygen delivery devices. Their TAVI proceeds as normal. An anaesthetist monitors all patients closely and makes adjustments to oxygen and sedation levels as required. Information is collected during the procedure and recovery period and patients answer a short questionnaire

during their recovery. Patients' involvement in the study ends when they are discharged from hospital.

What are the possible benefits and risks of participating?
Patients may or may not benefit from participating. Patients in the HFNO group may benefit if their blood oxygen levels are improved. Future patients may benefit if HFNO is shown to improve the care, safety and comfort of patients undergoing TAVI under conscious sedation. There is always a risk of discomfort with the use of any oxygen device. With HFNO this can include feeling hot, stomach bloating or having a dry nose and mouth.

Where is the study run from?
Royal Papworth Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to November 2020

Who is funding the study?
Fisher and Paykel Healthcare Limited

Who is the main contact?
Claire Matthews
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
41251

Study information

Scientific Title
A randomised controlled trial of high-flow nasal oxygen (HFNO) vs standard oxygen therapy in patients undergoing transfemoral transcatheter aortic valve implantation (TAVI) under conscious sedation

Study objectives
The primary aim is to determine if high flow nasal oxygen (HFNO) in patients undergoing transcatheter aortic valve implantation (TAVI) under conscious sedation compared to standard oxygen delivery (2 litres via nasal specs) improves patients' gas exchange as measured by blood tests of oxygen availability.

Secondary aims are to determine whether the use of HFNO:
1. Reduces the number of times either the patient or the anaesthetist has to interfere with the sedation level, airway or oxygen delivery device (e.g. verbal commands/chin lift by the anaesthetist or hand movement towards the oxygen delivery device by the patient)
2. Improves cerebral oxygenation by reducing the number of and severity of cerebral desaturation episodes
3. Is associated with reduced stay in recovery (hours)
4. Is associated with reduced admissions to the intensive care unit
5. Is associated with a reduced requirement for conversion to general anaesthesia (GA), escalation of respiratory support, tracheal intubation or pulmonary complication

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2019, East of England - Cambridge East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Tel: +44 (0)207 104 8101; Email: NRESCommittee.EastofEngland-CambridgeEast@nhs.net), ref: 19/EE/0104

Study design
Randomised; Interventional; Design type: Prevention, Device, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Oxygen supply during transcatheter aortic valve implantation (TAVI)

Interventions
Screening and consent:
Patients scheduled to undergo a TAVI procedure will be identified by a member of the study team. Patients meeting the entry criteria will be provided with a patient information sheet and given at least 24 hours to consider participation. Prior to their TAVI procedure, a member of the research team will meet them to answer any questions and ask for consent to take part in the study.

Randomisation:
Patients will be transferred to the cardiac catheterisation laboratory for their TAVI procedure, baseline measurements will be taken and then the randomisation performed. Patients will be randomised in a 1:1 ratio to receive either:
1. High Flow Nasal Oxygen (up to 50 l/min warmed and humidified using the Optiflow delivery system)
2. Standard Oxygen Therapy (2 l/min increasing to 8 l/min as required, delivered via nasal specs)

Procedure:
Once the allocated oxygen therapy has begun, patients will be sedated and the TAVI procedure will commence as per standard hospital protocol:
1. Oxygen started depending on randomisation allocation
2. Conscious sedation is started (by remifentanil intravenous infusion)
3. Regional block sited on side of TAVI procedure.
4. Transthoracic echocardiogram performed.
5. An arterial blood gas (ABG) sample is taken for analysis and repeated every 20 min or as determined according to clinical need.
6. TAVI valve implantation takes place.
7. Sedation stopped once confirmed that no bleeding from femoral artery. If surgical intervention required (e.g. due to damage to femoral artery), this can normally take place under sedation and regional block, but occasionally general anaesthetic may be required.

Follow-up:
Following the TAVI procedure patients will be transferred to the recovery area and, once the standard recovery criteria are met, then transferred to the ward. Clinical data will be recorded whilst patients are on the recovery area and ward. Patients will also be asked to verbally complete a short patient comfort questionnaire (three questions with multiple choice answers) whilst in the recovery area. Patients will be followed up until the standard discharge criteria are met and the patient can be discharged home.

Serious adverse events (SAEs):
Non-serious Adverse Events will not be recorded unless they form part of the clinical event dataset. All Serious Adverse Events (SAEs) occurring between randomisation and the end of follow-up will be reported to Papworth Clinical Trials Unit Collaboration (PTUC) within 24 hours of knowledge of the event.

Data handling:
The trial will be conducted according to Good Clinical Practice and PTUCs own standard operating procedures to ensure the monitoring and safety of trial participants and data validity. A secure, restricted-user, trial-specific database will be developed at PTUC. A member of the research team will enter the data into the database, which will only be accessible by the trial personnel.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure

The partial pressure of oxygen dissolved in the blood (PaO2) taken from an arterial blood gas sample during the procedure

Secondary outcome measures
1. The number of desaturations (defined as SpO2 <93% for >10 seconds or SpO2 drop more than 5% from baseline for >10 seconds) at any time during the procedure measured by pulse oximetry
2. Time spent on the Recovery ward post-procedure measured in hours
3. Number of patients requiring conversion to general anaesthesia during the procedure
4. Duration of oxygen provision during and post-procedure measured in hours
5. Patient-reported comfort measured using the Patient Comfort Questionnaire post-procedure
6. Time spent in hospital measured in days at discharge

Overall study start date
01/01/2018

Completion date
06/11/2020

Eligibility

Key inclusion criteria
1. Able to provide informed consent
2. Adult patients (> 18 years)
3. Patients undergoing an elective transfemoral TAVI procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 70; UK Sample Size: 70

Total final enrolment
72

Key exclusion criteria
1. Contraindication to HFNO such as a nasal septum defect
2. Participation in another randomised controlled trial

Date of first enrolment
01/05/2019

Date of final enrolment
07/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type

Industry

Funder Name
Fisher and Paykel Healthcare Limited

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. The researchers will invite participants at the end of the trial to come to a presentation about the results and impact of the trial and provide them with a written report of the trial, and ask them for feedback and thank them for their participation

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr A Klein (andrew.klein@nhs.net) once the study has been published on contacting Dr Klein.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v3.4	15/01/2019	30/04/2019	No	No
Results article		14/04/2023	17/04/2023	Yes	No
HRA research summary			26/07/2023	No	No