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High-flow nasal oxygen (HFNO) in high-risk cardiac surgical patients

Submission date
15/07/2015

Recruitment status
No longer recruiting

Registration date
16/07/2015

Overall study status
Completed

Last Edited
11/07/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
High-risk patients with lung disease who have heart (cardiac) surgery are at significant risk of developing complications after surgery (postoperative complications) leading to a prolonged hospital stay. One way of reducing the risk of lung complications is to treat patients with non-invasive ventilation or continuous positive airways pressure after their surgery. However, this often requires admission to a high dependency unit or intensive care, and is uncomfortable because of the need for a tight fitting mask, as well as being labour intensive and costly. High-flow nasal oxygen is a new alternative as it provides warmed humidified oxygen at high flow, and also has been shown to assist breathing and improve recovery. It is comfortable during use and indeed may be more comfortable than standard (dry) oxygen via a facemask or nasal prongs. It may be given on a normal ward, however its routine use in high-risk patients with lung conditions such as asthma, chronic obstructive pulmonary disease, recent chest infections and heavy smokers has not been tested before. The aim of this study is to determine if prophylactic high-flow nasal oxygen therapy in cardiac surgical patients at high risk of developing postoperative pulmonary complications is associated with a shorter hospital stay.

Who can participate?
Adults (over 18) undergoing cardiac surgery and are at risk of developing respiratory complications after surgery.

What does the study involve?
Before surgery, each participant performs a six-minute walking test under the supervision of a physiotherapist. This simple test measures how far patients can walk in six minutes. Additionally, patients have spirometry testing which is used to assess how well the lungs work by measuring how much air the patient inhales and exhales and how quickly they exhale. Patients then have their surgery under general anaesthesia. After the operation, they are looked after following the study recovery protocols, which includes pain relief, regular physiotherapy, early mobilisation and eating and drinking, and removal of chest drains and tubes as soon as possible. On arrival in the critical care area after their surgery, participants are randomly assigned to one of two groups. Those in group 1 are given supplemental oxygen via a soft facemask (control group). Those in group 2 are given supplemental oxygen via high-flow nasal cannulae (intervention group). Participants are given oxygen for at least 24 hours after surgery. Participants who

develop breathing difficulty receive treatment based on their clinical need. On the fifth or sixth day after surgery, they all do the walking test and spirometry test again. A short questionnaire is used to determine if there is any difference in how the participants feel they have recovered before they leave hospital and how quickly they returned to normal activities after discharge, and also to evaluate how they tolerated either the facemask or high flow nasal cannulae.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
September 2015 to March 2017

Who is funding the study?
Fisher & Paykel Healthcare Limited

Who is the main contact?
Miss Fiona Bottrill

Contact information

Type(s)
Public

Contact name
Miss Fiona Bottrill

Contact details
Papworth Hospital NHS Foundation Trust
Papworth Everard
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19338

Study information

Scientific Title

A randomised controlled trial of high-flow nasal oxygen (Optiflow™) and standard oxygen therapy in high-risk patients after cardiac surgery

Study objectives
Patients post cardiac surgery are at risk of respiratory complications, and consequently prolonged length of hospital stay, delayed recovery and poorer outcomes. The incidence of respiratory complications is increased in patients with previous respiratory disease such as asthma or chronic obstructive pulmonary disease (COPD), or current smokers. Our hypothesis is that prophylactic use of nasal high flow oxygen in high risk cardiac surgical patients for 24 hours after surgery will reduce the length of hospital stay and improve functional patient reported recovery. Improved functional recovery may be associated with fewer respiratory complications and may subsequently lead to earlier discharge from hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands – Derby, 15/06/2015, ref: 15/EM/0251

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiac Surgery

Interventions
Before surgery, each participant performs a six-minute walking test under the supervision of a physiotherapist. This simple test measures how far patients can walk in six minutes. Additionally, patients have spirometry testing which is used to assess how well the lungs work by measuring how much air the patient inhales and exhales and how quickly they exhale. Patients then have their surgery under general anaesthesia. After the operation, they are looked after following the study recovery protocols, which includes pain relief, regular physiotherapy, early mobilisation and eating and drinking, and removal of chest drains and tubes as soon as possible. On arrival in the critical care area after their surgery, participants are randomly assigned to one of two groups. Those in group 1 are given standard supplemental oxygen therapy (soft oxygen mask or

nasal cannulae) (control group). Those in group 2 are given supplemental oxygen via high-flow nasal cannulae (intervention group). Participants are given oxygen for at least 24 hours after surgery. Participants who develop breathing difficulty receive treatment based on their clinical need. On the fifth or sixth day after surgery, they all do the walking test and spirometry test again. A short questionnaire is used to determine if there is any difference in how the participants feel they have recovered before they leave hospital and how quickly they returned to normal activities after discharge, and also to evaluate how they tolerated either the facemask or high flow nasal cannulae.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Hospital length of stay (days)

Secondary outcome measures
1. Early postoperative functional recovery, determined by 6 minute walk test (6MWT)
2. Early postoperative lung function, tested by spirometry
3. Intensive care unit (ICU) length of stay (days)
4. Requirement for escalation of respiratory support and ICU re-admission

Overall study start date
01/09/2015

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Undergoing elective cardiac surgery (coronary artery bypass grafting, valve surgery or both)
3. One or more patient related risk factor for postoperative pulmonary complications (COPD, asthma, lower respiratory tract infection in last 4 weeks, body mass index=35 kg/m2 current (last 6 weeks) heavy smokers (> 10 pack years))
4. Capable of performing a 6MWT. The 6MWT is a clinical exercise test, and is popular in clinical practice because it aids clinical decision making, and because of the belief that it provides a better estimate of functional capacity than resting cardiorespiratory measurements. The 6MWT is the most popular clinical exercise test, which is used for postoperative evaluation after lung surgery and has also been validated in cardiac surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 74; UK Sample Size: 74

Key exclusion criteria
1. Contraindication to high flow nasal oxygen such as nasal septal defect
2. Not met extubation criteria by 10am the day after surgery (Day 1)
3. Need for CPAP preoperatively

Date of first enrolment
01/09/2015

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital NHS Trust
Clinical Trials
Papworth Hospital NHS Foundation Trust
Papworth Everard
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Trust

Sponsor details
Papworth Everard
Cambridge
England

United Kingdom
CB3 8RE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Fisher & Paykel Healthcare Limited

Results and Publications

Publication and dissemination plan
The aim is to publish the study results by 01/12/2017.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/03/2018	11/07/2018	No	No
HRA research summary			28/06/2023	No	No