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Effect of postoperative nasal ventilation in patients undergoing coronary artery bypass grafting (CABG)

Submission date
06/04/2011

Recruitment status
No longer recruiting

Registration date
05/07/2011

Overall study status
Completed

Last Edited
11/11/2013

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Coronary artery bypass graft (CABG) surgery is well known to affect the lungs in a number of ways, mainly as a result of lung basal atelectasis (alveoli collapsing at the bottom of the lung), which is usually seen in the first 48 hours after an operation. Patients can end up staying in hospital longer as a result of this additional problem. We have carried out a study using a non-invasive technique (non-invasive ventilation [NIV] with bilevel positive airway pressure [BiPAP]) in patients undergoing CABG with cardiopulmonary bypass, in order to compare the results of using NIV with BiPAP with using routine standard care.

Who can participate?
Participants were patients referred for "on-pump" first time CABG surgery with mild hypothermia (body temperature between 32 and 35°C).

What does the study involve?
Patients were placed at random into one of two groups: either NIV using BiPAP or routine standard care following the operation. Lung performance was measured by levels of carbon dioxide gas (PCO2) and a test of lung volume (FEV1).

What are the possible benefits and risks of participating?
Participants in the NIV with BiPAP group may have a shorter time in hospital with fewer complications. We do not anticipate additional benefits for the routine care group than normally expected. We do not anticipate any side effects from the NIV with BiPAP treatment.

Where is the study run from?
Hammersmith Hospital (London, UK).

When is study starting and how long is it expected to run for?
The study will run from February 2008 to February 2011.

Who is funding the study?
Imperial College Healthcare NHS trust and Respironics (now Phillips).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
INDP1073

Study information

Scientific Title
Effect on speed of recovery of postoperative nasal ventilation compared to conventional management in patients undergoing coronary artery bypass grafting (CABG): a randomised controlled trial

Study objectives
1. That following CABG surgery post-operative noninvasive ventilation (NIV) support with bilevel positive airway pressure (BiPAP) in all patients may significantly improve respiratory physiology.
2. That this will reduce complications, intensive care unit (ICU) admissions and duration, and length of hospital admissions when compared to conventional management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hammersmith and Queen Charlotte's & Chelsea Research Ethics Committee approved on 04 September 2007, reference number: 07/Q0406/79

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Post-operative care of coronary artery bypass graft (CABG) patients

Interventions
Nasal bilevel positive airway pressure (BiPAP) support added to routine post-operative care compared to routine post-operative care

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hospital length of stay from day of operation to day of fitness-to-discharge-until day when judged fit-for-discharge on the basis of clinical criteria

Secondary outcome measures
1. Lung function and blood gases-Lung function:
1.1. Pre-op lung function is done within 4 weeks of the operation (bed-side spirometry, and then formal departmental spirometry). In patients with a significant obstructive defect {defined as an FEV1 < 70% or [forced expiratory volume in one second (FEV1)/forced vital capacity (FVC)] of < 70%}, spirometry is then done before and after bronchodilator administration as well as body plethysmography for lung volumes and gas transfer.

1.2. Respiratory muscle strength, measured as mouth pressures [maximum inspiratory pressure (MIP) and maximum expiratory pressure (MEP)] have been measured on majority of patients.
1.3. Post-operative lung function is measured on day 1, 2 and 3 by bed-side spirometry with documentation of oxygen (O2) saturation and fraction of inspired oxygen (FiO2) given to patient.
1.4. Arterial Blood gases:
Are measured preoperatively as a baseline, just before the operation. ABG are measured after the operation at the time of ex-tubation, 1hour later, 12 hours later and 24 hours from the time of ex-tubation. The Fio2 is documented for each measurement
2. Intensive treatment unit (ITU) length of stay
3. Occurrence of complications

Overall study start date
01/11/2007

Completion date
31/03/2011

Eligibility

Key inclusion criteria
Any patient accepted for elective CABG surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Pre-existing significant renal (creatinine>200 umol/L), hepatic or haematological disease
2. Poor left ventricular function
3. Chronic infection
4. Emergency surgery

Date of first enrolment
01/11/2007

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Respiratory Medicine
London
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W12 0HS

Sponsor information

Organisation
R&D Hammersmith Hospital (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05jg8yp15

Funder(s)

Funder type
Industry

Funder Name
Imperial College Healthcare NHS trust (UK)- internal funding

Funder Name

Respironics (now Phillips) (UK)- supplied nasal ventilators (BiPAP), consumables and funded staff training

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2013		Yes	No