

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

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<b>Registration date</b> 05/07/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/11/2013	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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 (PCO<sub>2</sub>) and a test of lung volume (FEV<sub>1</sub>).

### 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 Respiroics (now Phillips).

Who is the main contact?  
Dr Philip Ind  
p.ind@imperial.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Philip Ind

**Contact details**  
Respiratory Medicine  
Imperial College NHS Trust  
Hammersmith House  
Du Cane Road  
London  
United Kingdom  
W12 0HS  
+44 (0)20 8383 3269  
p.ind@imperial.ac.uk

## Additional identifiers

**Protocol serial number**  
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

## **Primary study design**

Interventional

## **Study design**

Randomised controlled trial

## **Study type(s)**

Screening

## **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(s)**

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

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

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

## **Completion date**

31/03/2011

# Eligibility

## Key inclusion criteria

Any patient accepted for elective CABG surgery

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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

United Kingdom

England

## Study participating centre

Respiratory Medicine

London

United Kingdom

W12 0HS

# Sponsor information

## Organisation

R&D Hammersmith Hospital (UK)

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

**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?
<a href="#">Results article</a>	results	01/10/2013		Yes	No