

High flow nasal oxygen after lung resection surgery

Submission date 19/06/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/06/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/08/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Patients who undergo lung resection surgery are at risk of respiratory complications after the operation. One established method of reducing the risk of these complications is to treat patients with non-invasive ventilation (NIV) after the operation. However, this often requires admission to a high dependency unit or intensive care (ICU), and is so is costly and labour intensive. Nasal high flow oxygen in addition to other possible benefits can provide a low level of positive airway pressure similar to NIV, but is easy enough to use that it may be administered on a normal ward. The aim of this study is to find out whether the use of nasal high flow oxygen after lung resection surgery can improve patients early functional outcome and recovery. The 6-minute walking test (6MWT) is used to determine this, because it is a measure of patients functional ability, i.e. it represents how much they can do. It is therefore directly relevant to their recovery. Patients' recovery is also assessed subjectively using a validated recovery questionnaire.

Who can participate?

Adult patients who are scheduled to undergo partial single lung resection.

What does the study involve?

Before the operation, each patient performs a 6MWT and spirometry test under the supervision of a physiotherapist. The 6MWT is an exercise test where patients measure how far they can walk in 6 minutes. Spirometry measures the possible strength of the patients breathing. Patients thereafter undergo their surgery and have anaesthesia as they would normally. After the operation they are treated in accordance with the enhanced recovery program for thoracic surgery already established at the hospital, incorporating adequate pain relief, postoperative physiotherapy, early mobilisation, good nutrition, and appropriate removal of chest drains and tubes. On arrival in the recovery room after their surgery, patients are randomly allocated to receive supplemental oxygen via a soft facemask (standard group), or via high flow nasal cannulae (intervention group). Patients are administered oxygen for at least 24 hours after the operation. Patients who develop breathing difficulties receive treatment as required based on their clinical need. Spirometry is tested daily after the operation. This takes about 5 minutes. On the third day after the operation they repeat the 6MWT. Additionally the x-rays of patients are compared after the operation to see if one group has more areas of lung collapse than the other

group. Pain scores and the amounts of painkillers required are also compared. A short questionnaire is used to determine whether there is any difference in how patients feel they recovered, and to evaluate how they tolerated either the facemask or high flow nasal cannulae.

What are the possible benefits and risks of participating?

Benefits include comfortable and improved breathing if treated with high flow oxygen which is heated and humidified, and may speed up and improve recovery from surgery. Risks include some patients may find high flow oxygen uncomfortable when it is started and it will need adjusting. Some patients may get air trapped in the stomach very occasionally, which should get better on its own. No other risks identified up to now.

Where is the study run from?

Papworth Hospital (UK)

When is the study starting and how long is it expected to run for?

April 2014 to May 2015

Who is funding the study?

The National Institute of Academic Anaesthesia (NIAA) (UK)

Who is the main contact?

Dr Andrew Klein

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

16802

Study information

Scientific Title

The efficacy of prophylactic nasal high flow oxygen compared with standard oxygen therapy in improving early postoperative recovery after lung resection surgery

Study objectives

That the routine administration of nasal high flow oxygen post lung resection surgery leads to improved early functional recovery as determined by a 6-minute walk test, compared with usual care low flow facemask or nasal prongs oxygen therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Derby, 19/03/2014, ref. 14/EM/0105

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

Interventions

Patients will perform a 6-minute walk test and spirometry before their surgery. In addition, they will complete the Post-operative Quality Recovery Scale (PQRS) recovery questionnaire. During their surgery they will be randomised using computer generated sequence by research and development staff not directly involved in the study. Patients will have either high flow nasal oxygen or standard oxygen administered in recovery, for a period of 24 hours initially. Post-operatively, the quality of recovery questionnaire will be completed on days 1, 2, and 7 post-operatively. Spirometry will be repeated on post-operative days 1 and 2, and the 6-minute walk test repeated on day 2.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

6-minute walk measured 2 days after surgery

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/05/2015

Eligibility

Key inclusion criteria

Adult patients undergoing elective lung resection surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients undergoing pneumonectomy
2. Patients who cannot undertake a 6MWT
3. Patients with a contraindication to nasal high flow oxygen
4. Patients who are treated with CPAP pre-operatively

Date of first enrolment

23/04/2014

Date of final enrolment

01/05/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Papworth Hospital NHS Foundation Trust

Cambridge

United Kingdom

CB23 3RE

Sponsor information

Organisation

Papworth Hospital NHS Trust (UK)

ROR

<https://ror.org/01qbebb31>

Funder(s)

Funder type

Research organisation

Funder Name

The National Institute of Academic Anaesthesia (NIAA); Grant Codes: WKR0-2013-0062

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?
Results article	results	01/02/2016		Yes	No
HRA research summary			28/06/2023	No	No