ISRCTN04561506 https://doi.org/10.1186/ISRCTN04561506

High flow nasal oxygen after lung resection surgery

Submission date	Recruitment status	[_] Prospectively registered
19/06/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/06/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/08/2017	Surgery	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
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 questionaire. 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 measure
6-minute walk measured 2 days after surgery

Secondary outcome measures
Not provided at time of registration

Overall study start date
23/04/2014

Completion date
01/05/2015

Eligibility

Key inclusion criteria
Adult patients undergoing elective lung resection surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64

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
England

United Kingdom

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

Sponsor information

Organisation
Papworth Hospital NHS Trust (UK)

Sponsor details
Papworth Everard
Cambridge
England
United Kingdom
CB3 8RE

Sponsor type
Hospital/treatment centre

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

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	01/02/2016		Yes	No
HRA research summary			28/06/2023	No	No