Endobronchial EZ-Blocker Compared to Left Sided Double-Lumen Tube for One-Lung Ventilation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON34895

Source
ToetsingOnline

Brief title
EZ Blocker vs. LDLT

Condition

- Respiratory tract therapeutic procedures

Synonym
one-lung ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: double lumen tube, endobronchial blocker, one-lung ventilation, thoracic surgery

Outcome measures

Primary outcome

The main study parameter is the incidence of malposition of a left sided DLT or the EZB. There are four time points were malposition are considered:

- Malposition detected by fiber optic bronchoscopy after blind insertion of the device
- Malposition detected by fiber optic bronchoscopy or ausculation after inflation of the bronchial cuff of the DLT or the balloon of the EZB (left and right)
- Malposition detected by fiber optic bronchoscopy or auscultation after repositioning the patient to lateral decubitus position (after inflation of the bronchial cuff of the DLT or the balloon of the EZB (left and right))
- Malposition detected by fiber optic bronchoscopy or visual inspection of the lung by the surgeon during surgery (Dislocation of the device)

Secondary outcome

Secondary study parameters are the ease and duration of insertion, the ease and duration of positioning and the quality and the duration of lung deflation.

The ease of insertion of the devices is qualitative variable: 1= excellent, 2= good, 3=average, 4=poor. If the insertion excellent, it can be explained why.

The quality of lung deflation is a qualitative variable, judged by the surgeon:

1= excellent, 2= good, 3=average, 4=poor. If the lung deflation is not excellent it can be explained why.

Other secondary parameters are the incidence of postoperative complains of sore throat and hoarseness, and a description of damage to laryngeal, tracheal and bronchial structures.

Study description

Background summary

Lung isolation is used to achieve one lung ventilation to facilitate thoracic surgery. Two methods are commonly used, a double lumen tube (DLT) or a bronchial blocker introduced through a single lumen tube. However, both techniques have advantages and disadvantages. Briefly, the DLT can be positioned faster and remains firmly in place, but is sometimes difficult or even impossible to introduce. The DLT is larger than a conventional single lumen tube and the incidence of postoperative hoarseness and airway injuries is higher. Compared to the DLT, bronchial blocking devices are more difficult to position and need more frequent intraoperative repositioning. These disadvantages of the existing devices for lung isolation prompted further development of the bronchial blocker concept. The design of a new Y shaped bronchial blocker, the EZ- Blocker® (AnaesthetIQ BV, Rotterdam, The Netherlands) (EZB), combines the advantages of both lung isolation techniques. The EZB has been evaluated in a porcine model, a mannequin, in a human corpse and in a clinical study. The EZB blocker is recently CE certified. There is not yet a clinical study that evaluates the efficacy and safety of the device.

Study objective

The aim of the study is to compare the ease of placement, the incidence of malpositioning and the quality of lung deflation of a left DLT and a EZB. Secondly, the incidence and severity of damage to laryngeal, tracheal and bronchial structures caused by the use of the DLT or the EZB is a target of the study.

Study design

The study is randomized, prospective and partially blinded.

The surgeon is blinded to the technique used when he has to give his opinion on the quality of the lung deflation. The lung specialist is blinded when he/she reviews the video*s of bronchi, trachea and larynx. The patient and the interrogator is blinded when he/she is interviewed for sore throat and hoarseness.

The study takes place at the Radboud University Nijmegen Medical Centre. Probably the study will start in the beginning of 2010 and it will end one year later.
Patients are recruited during their pre-operative assessment one week before their operation. Patients are randomized into two groups using a computer generated code prepared by a statistician.

The patients are treated equally regarding pre-operative preparations and per- and post-operative treatment, except the placement of the device for lung isolation. The placement of a double lumen tube is the standard clinical practice. Inspection by fiber optic bronchoscopy of the position of the device is routine. A check for injury caused by the device to the patient*s larynx, trachea or bronchus is often performed during final inspection of patient*s airway (e.g. suture inspection, removal of blood or secretions in the airway). The available hospital protocols (KWINT) are used for the preoperative assessment and per- and post- operative treatment. The study is performed by four anesthesiologists experienced with both techniques (wide experience with DLT and at least 5 placements of the EZ-blocker).

Intervention

Traditionally, single lung ventilation is obtained with a double lumen tube (DLT). In our institution a polyvinyl DLT (Broncho-cath, Mallinckrodt,) without carinal hook, is used. This type of tube exists of a tube with two lumen with two distal cuffs. One lumen (called the bronchial lumen) extends some distance further, has a slight curvature and has a small blue cuff. The other lumen (called the tracheal lumen) has a larger cuff. A DLT tube exists in four sizes and one can choose in a left or a right configuration. Almost always,we use a left sided DLT. A DLT has a much larger diameter than a standard single lumen endotracheal tube.

The EZ-blocker (EZB) is a semi-rigid catheter with two distal extensions, both with an inflatable cuff and a central lumen. It is intended for use in combination with a single lumen tube. After the EZB is advanced trough the distal end of the single lumen tube, both extensions spread out and find their way in the left and right main stem bronchi. The place where the two extensions are attached to the shaft now rests on the carina. Fiberoptic bronchoscopy should be used for proper positioning. After placement of the EZB, one of the cuffs can be inflated to obtain lung separation under direct visual inspection with fiberoptic bronchoscopy.

If placement of a DLT is unsuccesful it will be replaced by an EZB and if placement of an EZB is unsuccesful it will be replaced by an EZB.

Study burden and risks

Patients are under anaesthesia when one of the devices for lung isolation are placed. Participation in the study does not result in additional risks for the patient. There are no direct benefits for the participating patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

ASA physical status 1-3 patients requiring a left sided DLT for single lung ventilation

Exclusion criteria

Contraindications are lesions along the path of the left sided dubble lumen tube or the EZB, tracheal or mainstem bronchial stenosis and distorted carinal anatomy, anticipated difficult intubation (Mallampatti score >= 3) and history or presence of tracheostoma. Excluded are patients who require absolute lung separation or sleeve resection of mainstem bronchus.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	endobronchial EZ-blocker
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-02-2010

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL30799.091.09