Trial Description

Title

Analysis of patients' satisfaction and costs of video-assisted thoracoscopic surgery in local anaesthesia with analgosedation and spontaneous breathing in comparison to general anaesthesia with double-lumen tube and one-lung ventilation

Trial Acronym

PASSAT (PAtientS' SATisfaction in thoracic surgery)

URL of the trial

[---]*

Brief Summary in Lay Language

Minor surgery of the pleura and the lung can be performed in local or general anaesthesia, each of which has its own advantages and disadvantages. The patients' satisfaction with the respective anaesthesia has not been investigated yet. This is the primary goal of the study.

Brief Summary in Scientific Language

Minor thoracoscopic surgery, i.e. treatment of pleural effusions, biopsies and small peripheral pulmonary wedge resections, can be performed in local anaesthesia (LA), analgosedation and spontaneous breathing as well as in the current standard, general anaesthesia (GA) and one-lung ventilation. Whilst feasibility and safety have been demonstrated, very little is known about the patients’ satisfaction with local compared to general anaesthesia. Most data on satisfaction with LA are not comparative or do not meet psychometric criteria. The PASSAT trial (PAtientS’ SATisfaction in thoracic surgery – general vs. local anaesthesia) is a randomised controlled trial with a non-randomised side-arm. Patients with indication to minor thoracoscopic surgery and physical eligibility for GA and LA will be randomised to surgery in GA (control group) or LA (intervention group). Those who refuse to be randomised will be asked to attend the study on basis of their own choice of anaesthesia (preference arm) and will be analysed separately. The primary endpoint is the satisfaction according to a psychometrically validated questionnaire; secondary endpoints are complication rates, actual costs and cost-effectiveness. The study ends with 2x54 patients in the randomised arms.
PASSAT study is the first randomised controlled trial to systematically assess the patients’ satisfaction depending on LA or GA. The study follows an interdisciplinary approach. Its results may be applicable to other surgical disciplines, too. It is also the first cost study based on randomised samples. All patients will be monitored by intraoperative continous capnography.

Do you plan to share individual participant data with other researchers?

[---]*

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[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013661**
- Date of Registration in DRKS: **2018/03/23**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **195/2017 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1207-0233**

Health condition or Problem studied

- ICD10: **J90 - Pleural effusion, not elsewhere classified**
- ICD10: **C78 - Secondary malignant neoplasm of respiratory and digestive organs**
- ICD10: **D48 - Neoplasm of uncertain or unknown behaviour of other and unspecified sites**
- ICD10: **I31 - Other diseases of pericardium**

Interventions/Observational Groups

- Arm 1: **General anaesthesia, double-lumen tube, one-lung Ventilation (control group) - randomised arm**
- Arm 2: **Local anaesthesia, analgosedation, spontaneous breathing (intervention group) - randomised arm**
- Arm 3: **General anaesthesia, double-lumen tube, one-lung Ventilation (control group) - non-randomised / preference based arm**
- Arm 4: **Local anaesthesia, analgosedation, spontaneous breathing (intervention group) - non-randomised / preference based arm**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Patients' satisfaction, receiving VATS (Video Assisted Thoracoscopic Surgery), depending on the anaesthesia (local versus general), measured by means of the psychometrically validated questionnaire "ANP" ("Anästhesiologischer Nachbefragungsbogen für Patienten", Hüppe et al. 2003)

Secondary Outcome

- patients' satisfaction corrected by their expectations by means of the ANP at the first day after operation
- postoperative pain scales at discharge and follow-up measured as numeric rating scale from 0 to 10
- postoperative complication rates including postoperative cognitive disorders (POD), at the time of discharge, by means of a checklist
- C-reactive protein levels postoperatively during the hospital stay, measured in mg/l
- comparison of intraoperative capnography (continous measurement of endtidal carbon dioxide in mmHg) and correlation with the preoperative lung function (forced expiratory volume in one second)
- the surgeon's and the anaesthetist's satisfaction with the feasibility of the operation in local anaesthesia as numeric rating scale from 0 to 10
- comparison of standard data: Operation time (minutes), blood loss (ml), blood gas analysis (paCO2 in mmHg), duration of chest tube drainage (days), hospital length of stay (days)
- comparison of costs by measuring both, staff and material, during the postoperative hospital length of stay

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Lungenklinik Merheim, Kliniken der Stadt Köln gGmbH, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/06/01**
- Target Sample Size: **108**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Age at least 18 years
Indication for VATS
1. VATS with partial pleurectomy
2. VATS with talcum pleurodesis (with or without partial pleurectomy)
3. VATS with permanent chest tube (with or without partial pleurectomy)
4. VATS with local lymphnodectomy of hilus or mediastinum
5. VATS with peripheral wedge resection
6. VATS with pericardial window
Patient suitable for local as well as general anaesthesia
Informed consent

Exclusion criteria

- Systematic lymphadenectomy
- Extensive lung resection
- Expected difficult airway
- Emergent surgery
- Severe coagulation disorders (INR > 1.5, PTT > 40sec)
- Previous ipsilateral radiation or surgery
- suggested need for thoracotomy in the preoperative planning
- COPD with severe impairment of lung function (FEV1 < 30%, DLCO / VC < 30%)
- Pregnancy and lactation
- simultaneous or recent (< 30 days) participation in another interventional Trial
- Persons who are in dependence or employment relationship with the sponsor or the investigators
- Incapable patients

Addresses

■ **Primary Sponsor**

Thoraxchirurgie, Lungenklinik
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51109 Köln
Germany

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Lungenklinik, Kliniken der Stadt Köln gGmbH, Standort Merheim
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Institutional budget, no external funding (budget of sponsor/PI)

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Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- trial protocol (mandatory for transfer to Studybox) **Rationale and design of PASSAT — patients' satisfaction with local or general anaesthesia in video-assisted thoracoscopic surgery: study protocol for a randomised controlled trial with a non-randomised side arm**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*