Trial Description

Title

Analysis for changing the arterial-to-end-tidal CO2 difference under pneumoperitoneum (PP)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

It should be examined whether, after conditioning of the PP an increase in the arterial-to-end-tidal CO2 difference occurs, how it develops in the course of PP and adjust what change after completion of the PP. Furthermore, a difference in the amount of increase of artetiellen-to-end-tidal CO2 difference are calculated in dependence on the body weight.

Brief Summary in Scientific Language

The aim of the study is to determine a change in the arterial-to-end-tidal CO2 difference under PP. The change in arterial-to-end-tidal CO2 difference should be at least 2 mmHg compared before induction of PP at the time immediately after induction of PP. An existing at the beginning of the anesthesia base difference in the arterial-to-end-tidal CO2 difference is to be shown. The change in CO2 difference should show a dependence on body weight, ie with higher BMI should be larger the deviation of the CO2 difference. It is to be observed, as the CO2 difference behaves during the operation and after completion of the PP. The possible effect of a recruitment maneuver (RM) and subsequent Positive End Expiratory Pressure (PEEP) before induction of PP is the focus.

Organizational Data

- DRKS-ID: **DRKS00006731**
- Date of Registration in DRKS: **2014/09/16**
- 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.: **98/14 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1160-1325**

Health condition or Problem studied

- Free text: **Laparoscopic operation**

Interventions/Observational Groups

- Arm 1: **1. Determination of arterial CO2 content by arterial blood gas analysis at various time points**
  - After induction of anesthesia
  - Before performing a recruitment maneuver (RM),
  - After completion of the RM
  - Before induction of PP,
  - Immediately after induction of PP and
  - During which time in 30 minute intervals
  - Once after completion of the PP

  2. At the same time, to all the above-mentioned Times, the measurement of the end-tidal CO2 concentration in the breathing gas.

  3. Relevant circulatory and respiratory parameters of a general anesthesia will be recorded continuously

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The aim of this study is to investigate whether, after creating a pneumoperitoneum during laparoscopic surgery an increase in the arterial-to-end-tidal CO2 concentration was recorded
1. Determination of arterial CO2 content by arterial blood gas analysis at various time points
- After induction of anesthesia

- Before performing a recruitment maneuver (RM),
- After completion of the RM
- Before induction of PP,
- Immediately after induction of PP and
- During which time in 30 minute intervals
- Once after completion of the PP

Secondary Outcome

Occur Study about the occurrence of differences in the range of the CO2 difference between patients with normal weight, overweight and obese

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie und Intensivtherapie, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/02**
- Target Sample Size: **35**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

1. Age: 18 - 75 years
2. Gender: male and female
3. race: caucasian
4. Body weight: BMI from 18
5. patients undergoing clinically indicated laparoscopic surgery
6. assent to necessary measures (arterial access or arterial puncture) with the written consent

Exclusion criteria

1. reduced lung function (FEV1 / VC <70% and FEV1 <80%)
2. COPD, Z.n. Status asthmaticus
3. Third right-to-left shunt or left-to-right shunt
4. pneumonia, pulmonary edema or state after pulmonary embolism
5. interstitial lung diseases
6. large pleural effusions
7. heart failure (NYHA III and IV)
8. systolic blood pressure <100 mmHg and diastolic <50 mmHg, volume depletion
9. decompensated liver or kidney disease
10. infection within the last 14 days
11. Contraindications to arterial access or arterial puncture (eg Allen test)
12. Refusal to participate in the study by the patient

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

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

Trial Publications, Results and other documents

** 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.*