

Trial Description

Title

Hemodynamic implications of laparoscopic surgery in Neonates and Infants compared to the open approach

Trial Acronym

LiDCOlapScop

URL of the trial

<http://Keine>

Brief Summary in Lay Language

The purpose of this clinical study is to investigate whether changes in cardiac circulatory system (cardiac output, blood pressure behavior) take place in children that undergo an abdominal operation, either as part of a laparoscopic procedure without any major incision in the abdominal wall (= so-called keyhole surgery) or by opening the abdominal wall (= so-called open surgery). After induction of general anesthesia (= anesthetic) and the routine insert an arterial cannula the LiDCO device is plugged into the surveillance monitor, not connected to their child. To calibrate this system a transthoracic cardiac ultrasound (= external) is conducted before the operation starts. The only, just because of the study performed actions are the heart ultrasound examination and the attachment of the LiDCO device to the patient monitor, all so-called non-invasive measures, not the body penetrating or hurtful measures.

Brief Summary in Scientific Language

The application of pulse contour analysis technique, which provides changes in stroke volume for each heart beat by calculating the nominal stroke volume from a print volume transform the radial artery pressure waveform, is safe and is approved for use in patients since 2003 as a minimally invasive hemodynamic monitoring of cardiac output approved. The LiDCO device is particularly suitable for patients who have only one arterial and venous access (peripheral or central). The present study may provide information whether the application of this minimally invasive hemodynamic monitoring system, the evaluation and treatment of the volume status of the patient intraoperatively is improved in neonates and infants undergoing laparoscopic or open abdominal surgery. Since the pulse contour analysis via LiDCO hemodynamic monitoring, by measuring the "beat-to-beat" cardiac output and oxygen delivery (without the need of advanced invasive measures), improving the global supply of oxygen can be maximized without the risk of fluid overload. This research provides a hemodynamic foundation, which enable new diagnostic possibilities and can have a significant impact on laparoscopic surgery, so this particular group of patients of very sick newborns and infants, these invasive procedures can be performed safely.



Organizational Data

- DRKS-ID: **DRKS00009447**
- Date of Registration in DRKS: **2015/10/27**
- 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.: **1519/2015 , Ethikkommission der Medizinischen Universität Wien**

Secondary IDs

Health condition or Problem studied

- Free text: **Hemodynamic implications of laparoscopic surgery**

Interventions/Observational Groups

- Arm 1: **Hemodynamic parameters during open abdominal surgery.**
- Arm 2: **Hemodynamic parameters during laparoscopic surgery.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To describe the hemodynamic changes (via LIDCO) in Neonates and infants compared in laparoscopic versus open approach

Secondary Outcome

There are respiratory changes while mechanical ventilation (VT;PIP) in patients with laparoscopic surgery

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Wien**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/01**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Months**
- Maximum Age: **12 Months**

Additional Inclusion Criteria

Major abdominal surgery, laparoscopic or open approach, in Neonates and infants (aged \leq 1 year)

Exclusion criteria

Parent's refusal of participation of their child in the study

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 planned**
- 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.