**Protocol synopsis of the ADIPO-Vent trial**

German clinical trials register number DRKS00004199

**Title of the study**

**Optimisation of perioperative mechanical ventilation in obese and normal weight patients by PEEP titration using electrical impedance tomography - a randomised controlled clinical trial**

**Study acronym**

ADIPO-Vent

**Generally understandable short description**

**Up to now, standard methods have been used for artificial ventilation, which is mandatory for patients undergoing laparoscopic surgery. Based on initial clinical results, it seems reasonable to adapt mechanical ventilation to the situation of the individual patient in order to reduce possible disadvantages, especially in obese patients. For example, individualizing mechanical ventilation settings enables to select exactly the ventilation pressure for mechanical ventilation that is neither too high (risk of overinflation or even rupture of alveoli) nor too low (risk of collapse of alveoli).**

**We hope that this individual ventilation adjustment by means of electrical impedance tomography will confirm the benefits on the function of the lungs and other organs after the operation. Furthermore, we are investigating whether the length of stay in the intensive care unit and the entire hospital stay can be reduced.**

**Brief scientific description**

**The present clinical trial is a prospective, randomised, controlled, monocentric pilot study comparing two different ventilation strategies during anaesthesia. The adjustment of mechanical ventilation is done by PEEP titration using electrical impedance tomography. The primary objective is to investigate whether the use of individualised lung-protective anaesthetic ventilation can significantly improve postoperative oxygenation and inspiratory oxygen fraction.**

**Secondary endpoints are end-expiratory lung volume, postoperative pulmonary and non-pulmonary organ function (determined by SOFA score, incidence of pulmonary and non-pulmonary complications and length of ICU and hospital stay.**

**Do you plan to make the participant-related data available to other researchers in anonymised form?**

[---]\*

**Organisational data**

* DRKS ID of the study: DRKS00004199
* Registration date in the DRKS: 27.07.2012
* Registration date in partner registry or other primary registry: [---]\*.
* Science-initiated study (IST/IIT): yes
* Vote of the Ethics Committee: Positive vote/approving assessment
* (Lead) Ethics Committee Template No.: 196-11-18042011 , Ethics Committee at the Medical Faculty of the University of Leipzig

**Disease/health problem investigated**

ICD10: E66.9 - Obesity, unspecified

**Intervention groups/observation groups**

* **Arm 1: mechanical ventilation using individualised ventilation parameters (PEEP).**
* **Arm 2: conventional strategy for mechanical ventilation**

**Characteristics**

* Study type: Interventional
* Study type non-interventional: [---]\*.
* Study design allocation: Controlled, randomised trial
* Blinding: Open
* Who is blinded: [---]\*
* Control: Active control (effective treatment of the control group)
* Study purpose: Other Group allocation: Parallel allocation Study phase: Not applicable
* Off-label drug use: Not applicable

**Primary endpoint**

**Post-operative oxygenation, measured by the quotient of arterial oxygen partial pressure (PaO2) and inspiratory oxygen fraction (FiO2) immediately before extubation.**

**Secondary endpoint**

**- Oxygenation at different time points**

**- End expiratory lung volume (EELV)**

**- postoperative pulmonary and non-pulmonary organ function (SOFA scores)**

**- the duration of ICU and hospital stay in days.**

**Countries in which study participants are recruited**

* DE Germany

**Recruitment locations**

* **Department of Anesthesiology and Intensive Care**, University of Leipzig Medical Center, Leipzig

**Recruitment**

* Planned/Actual: Actual
* (Planned/actual date) Inclusion of the first study participant: 01.11.2012
* Total planned number of study participants: 113 with half obese and half non-obese

**Inclusion criteria**

* Gender: Both male and female
* Minimum age: 18 years
* Maximum age: no maximum age

**Further inclusion criteria**

**- Age >= 18 years**

**- Obese group: obese (BMI ≥ 35 kg/m²)**

**- Normal weight group: BMI: 18.5 kg/m² to 25 kg/m²**

**- Planned surgical procedure under general anaesthesia with moderate or high risk of post-operative pulmonary complications (ARISCAT score ≥ 26).**

**- Signed informed consent**

**Exclusion criteria**

**- Planned neurosurgical, cardiac or thoracic surgery or ear, nose and throat or oral and maxillofacial surgery.**

**- Therapy-refractory haemodynamic instability**

**- Chronic or acute lung disease prior to surgery (e.g. COPD, pneumonia, ALI/ARDS)**

**- Pregnancy (pregnancy test required)**

**- severe cardiac disease (New York Heart Association classification III or IV, acute ischaemic event, persistent ventricular arrhythmia)**

**- any neuromuscular disease**

**- any surgical procedure lasting longer than 30 minutes under general anaesthesia in the last 30 days**

**- cardiac pacemakers or other implanted pacemaker or stimulator systems**

**Addresses**

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**Funding sources**

**Public funding institutions, tax-funded institutions (such as DFG, BMBF, etc.)**

**Federal Ministry of Education and Research Head Office Bonn Heinemannstr. 2**

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**Status**

Status of recruitment: Recruitment completed, follow up completed.

Actual date of study completion (LPLV): 07.12.2017

**Publications, study results and other study documents**

Nestler C, Simon P, Petroff D, Hammermüller S, Kamrath D, Wolf S, Dietrich A, Camilo LM, Beda A, Carvalho AR, Giannella-Neto A, Reske AW, Wrigge H. Individualized positive end-expiratory pressure in obese patients during general anaesthesia: a randomized controlled clinical trial using electrical impedance tomography. Br J Anaesth. 2017 Dec 1;119(6):1194-1205. doi: 10.1093/bja/aex192. PMID: 29045567.

Girrbach F, Petroff D, Schulz S, Hempel G, Lange M, Klotz C, Scherz S, Giannella-Neto A, Beda A, Jardim-Neto A, Stolzenburg JU, Reske AW, Wrigge H, Simon P. Individualised positive end-expiratory pressure guided by electrical impedance tomography for robot-assisted laparoscopic radical prostatectomy: a prospective, randomised controlled clinical trial. Br J Anaesth. 2020 Sep;125(3):373-382. doi: 10.1016/j.bja.2020.05.041. Epub 2020 Jul 19. PMID: 32665059.