

## Trial Description

### Title

**Reduction of ventilation invasiveness through combined organ support**

### Trial Acronym

**ADVOVENT (Advanced organ support for reduction of ventilation invasiveness)**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Artificial ventilation is a life-saving standard method at intensive care units which although can lead to further damage of the lung tissue by the use of long-lasting or too invasive ventilation.**

**Patients with pulmonary failure can not release the excess carbon dioxide sufficiently, so that a more invasive ventilation is required to guarantee the carbon dioxide removal by the lung.**

**The aim of the clinical trial is to find out, if the invasiveness of artificial ventilation can be reduced by removing excess carbon dioxide directly from the blood.**

**For that purpose the ADVOS System will be used. It is a multiple organ support system, based on a conventional renal replacement therapy, which has also the potential to remove carbon dioxide from the blood.**

### Brief Summary in Scientific Language

**The invasive artificial ventilation is one of the life-saving standard methods at intensive care units which although can negatively affect the outcome of patients next to long-term application.**

**High ventilation pressures and high tidal volumes (and high concentrations of oxygen) can lead to further damage of the lung tissue respectively a progression of the organ failure.**

**The aim of the clinical trial is to achieve a reduction of the invasiveness of artificial ventilation by extracorporeal removal of carbon dioxide (CO<sub>2</sub>) and correction of acidosis via the advanced organ support (ADVOS) system.**

**Patients with acute renal failure (and indication for dialysis) and simultaneously acute hypercapnic respiratory failure should be included into the described study.**

**The applied ADVOS procedure is a multi-organ support system based on a continuous venovenous haemodialysis with an albumin-enriched dialysis liquid. It is extended by a cycle (with variable pH value) for albumin-cleaning and toxin-removal. By that the elimination of protein-bound substances and carbon dioxide is possible, as well an adjustment of the pH value within comparatively wide limits.**

## Organizational Data

■ DRKS-ID: **DRKS00015874**



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- Date of Registration in DRKS: **2018/11/13**
- 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.: **D 526/18 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **J96 - Respiratory failure, not elsewhere classified**
- ICD10: **N17 - Acute renal failure**

## Interventions/Observational Groups

- Arm 1: **removal of carbon dioxide (CO2) and correction of acidosis via ADVOS treatment**

## Characteristics

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

## Primary Outcome

**Tidal volume (ml/kg ideal weight) to reach a ventilation with a pH value >7,30 and PaCO<sub>2</sub> < 60 mmHg (measured 6 hours after the beginning of the ADVOS treatment)**

### Secondary Outcome

- CO<sub>2</sub> removal achieved with the ADVOS system (ml/min)
- required alveolar ventilation per minute (l/min)
- pressure difference between airway plateau pressure and PEEP (cmH<sub>2</sub>O)
- change of power of ventilation (Joule/min)
- partial pressure of oxygen (mmHg)
- partial pressure of carbon dioxide (mmHg)
- pH

### Countries of recruitment

- DE Germany

### Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie und Operative Intensivmedizin, Kiel**

### Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/19**
- Target Sample Size: **10**
- 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

- **invasive controlled ventilation at acute hypercapnic respiratory failure (PaCO<sub>2</sub> > 45 mmHg)**
- **tidal volume > 6ml/kg ideal weight or driving pressure difference (delta p) > 15 cmH<sub>2</sub>O required to reach a pH value > 7,30**
- **acute renal failure (KDIGO II or III)**
- **clinical indication for continuous venovenous haemodialysis**
- **consent to participate in the clinical trial**



### Exclusion criteria

- severe acute hypoxemic respiratory failure (PaO<sub>2</sub>/FiO<sub>2</sub> ratio < 100 mmHg)
- moribund status (clinical evaluation)
- gravidity
- severe haemodynamic instability (heart rate < 40 bpm or > 150 bpm or mean arterial pressure < 65 mmHg or cardiac output < 5 l/min despite adequate therapy)
- elevated intracranial pressure

### Addresses

#### ■ Primary Sponsor

**Universitätsklinikum Schleswig-Holstein  
Arnold-Heller-Straße 3  
24105 Kiel  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

#### ■ Contact for Scientific Queries

**Klinik für Anästhesiologie und operative Intensivmedizin,  
Universtitätsklinikum Schleswig Holstein, Campus Kiel  
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URL: **<https://www.uni-kiel.de/anaesthesie/>**

#### ■ Contact for Public Queries

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### Sources of Monetary or Material Support

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

**Klinik für Anästhesiologie und operative Intensivmedizin**

**Arnold-Heller-Strasse 3**

**24105 Kiel**

**Germany**

Telephone: **043150020801**

Fax: **043150020804**

E-mail: [---]\*

URL: **<https://www.uni-kiel.de/anaesthesie/>**

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**HepaWash GmbH**

**Agnes-Pockels-Bogen 1**

**80992 München**

**Germany**

Telephone: **0800 43 72 92 74**

Fax: **+49 89 411 18 42 09**

E-mail: **info at hepawash.com**

URL: **<https://www.hepawash.com/>**

### Status

■ Recruitment Status: **Recruiting planned**

■ Study Closing (LPLV): [---]\*

### Trial Publications, Results and other documents

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Date of Registration in DRKS: **2018/11/13**

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**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

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*\* 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.*