

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Non-invasive haemodynamics

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Specialized parameters of circulatory and cardiac function (cardiac hemodynamics), for example cardiac output, systemic vascular resistance, pulmonary capillary wedge pressure etc. help the intensive care specialist on the intensive care unit to monitor of cardiac function. Therapeutical interventions on grounds of evaluated hemodynamic data help to reduce cardiac stress levels or to reverse or stabilize cardiac decompensation. Up to now, these hemodynamic parameters could only be measured by invasive catheters like a central venous catheter and an indwelling specialized arterial catheter (PiCCO system) or a catheter in the pulmonary artery (PAC). This study examines the feasibility of measuring these specialized hemodynamic parameters by using a non-invasive transthoracic echocardiography approach (cardiac ultrasound). Furthermore, hemodynamic parameters that might have an effect on survival for intensive care patients are evaluated.

Brief Summary in Scientific Language

Invasive hemodynamic monitoring by pulmonary thermodilution using a pulmonary artery catheter (PAC) or by transpulmonary techniques (e.g. PiCCO®-system) is routinely used in critically ill patients. Critical care echocardiography (CCE) is a relatively new, non-invasive technique that is increasingly employed to evaluate hemodynamic states. A number of limitations - several quite severe - apply to all these techniques: PAC and PiCCO® cannot be used in patients with relevant tricuspid regurgitation. Additionally, CCE does not yet provide quantitative hemodynamic data. By extending CCE with quantitative non-invasive hemodynamic assessments, we would like to obtain valid data for hemodynamic parameters which until now could only be quantified with thermodilution methods. We plan to plot hemodynamic parameters in six-dimensional web graphs to visualize the hemodynamic profiles of various compromised hemodynamic states. This should simplify clinical decision-making and help to identify dedicated treatment targets. Secondly, we will measure the effect of hemodynamic parameters on survival in the intensiv care unit.



Organizational Data

- DRKS-ID: **DRKS00010208**
- Date of Registration in DRKS: **2016/04/25**
- 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.: **11/12/13 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I00-I99 - Diseases of the circulatory system**

Interventions/Observational Groups

- Arm 1: **Intervention group will be subjected to an transthoracic echocardiogram for determination of hemodynamic parameters (cardiac output, cardiac index, pulmonary capillary wedge pressure, systemic vascular resistance, systemic vascular resistance index, left atrial pressure etc.) on the third day of the intensive care stay. Hemodynamic data are plotted into six-dimensional web charts (hemodynamic profiling) for visualizing hemodynamic states and identification of specific treatment targets. Subsequently, interventions will be directed to reduce cardiac stress or stabilize decompensated hemodynamic states by pharmacotherapy (catecholamine therapy), change of respirator settings, volume therapy, negative fluid balance, administration of inotropic substances etc. according to the individual underlying hemodynamic states.**

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)**

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: **N/A**

■ Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- **Feasibility of evaluating hemodynamic parameters by non-invasive transthoracic critical care echocardiography on the third day of the intensive care stay**
- **Measurement of various hemodynamic parameters on the intensive care unit (cardiac output, cardiac index, pulmonary capillary wedge pressure, systemic vascular resistance, systemic vascular resistance index, left atrial pressure etc.) using non-invasive critical care echocardiography on the third day of the intensive care stay**

Secondary Outcome

- **Identification of hemodynamic parameters that influence patient survival in the intensive care unit (statistical correlation)**
- **Corelation of surrogate parameters of circulatory and cardiac function (e.g. mean arterial pressure etc.) with hemodynamic parameters (measured by an indwelling arterial catheter and non-invasive hemodynamic critical care echocardiography)**
- **Determination of the incidence of cardiac pathologies (e.g. relevant tricuspid insufficiency) that lead to invalid results of methods that determine hemodynamic parameters invasively using transthoracic echocardiography on the third day of the intensive care stay**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- **University Medical Center Georg-August-University, Department of Anesthesiology, Emergency and Intensive Care Medicine,, Göttingen**



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/24**
- Target Sample Size: **111**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

Consecutive patients admitted to the intensive care unit on the third day of the intensive care stay

Exclusion criteria

Cardiac admission diagnosis, palliative treatment

Addresses

■ Primary Sponsor

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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)**

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Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Study Closing (LPLV): **2014/07/31**

Trial Publications, Results and other documents

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**Deutsches Register
Klinischer Studien**

German Clinical
Trials Register

** 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.*