

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

Trial Description

Title

Critical care echocardiography as a routine versus an acute procedure for the detection and early treatment of cardiac pathologies

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

This current study evaluates the range and prevalence of echocardiographically detectable cardiac pathologies in intensive care patients.

ICU-patients above 18 years of age are included in the study on their third day in the intensive care unit.

Patients treated in a palliative concept and patients with a cardiac admission diagnosis are excluded from the study.

Included patients are subjected to a transthoracic expert echocardiographic evaluation on their third day of the ICU stay.

Echocardiographic results will be scientifically analysed and correlated with further apparative, clinical und laboratory tests.

The following target parameters will be evaluated:

- Range and prevalence of cardiac diseases in intensive care patients detected by cardiac ultrasonography
- Survival of intensive care patients with cardiac diseases
- Statistical analysis for the presence of cardiac diseases by ECGs and lung x-ray interpretation
- Quality of cardiac ultrasonography images acquired in the ICU
- Prediction of cardiac diseases by special scoring systems in the intensive care unit

Brief Summary in Scientific Language

In addition to the brief summary in lay language the following parameters will be scientifically evaluated:

- Range and prevalence of cardiac pathologies in ICU patients by transthoracic

echocardiography

- **Survival of ICU patients with echocardiographically detectable cardiac pathologies**
- **Sensitivity, specificity, positive predictive value, negative predictive value for the presence of cardiac pathologies detected by ECG and chest x-ray interpretation**
- **Transthoracic image quality in ICU patients**
- **Prediction of cardiac pathologies by established ICU parameters (SAPS II; days in intensive care, etc.)**

Organizational Data

- DRKS-ID: **DRKS00009746**
- Date of Registration in DRKS: **2016/02/10**
- 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: Patients that met the inclusion criteria will be subjected to an extensive expert echocardiographic evaluation of cardiac pathologies on the third day of their ICU stay. The following tests will be conducted:**
 - **extensive expert echocardiographic evaluation by transthoracic echocardiography on the third day of the ICU stay**
 - **ECG and chest x-ray analysis by the attending consultant and resident (for later correlation with echocardiographic pathologies)**
 - **questionnaire answered by the attending consultant and resident regarding relevance and usefulness of the echocardiographic evaluation.**
- No invasive tests tests will be conducted.**



Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Evaluation of the range and prevalence of cardiac pathologies in ICU patients as following:

- **Range and prevalence of cardiac pathologies in ICU patients by transthoracic echocardiography (extensive expert echocardiographic evaluation on the third day in the intensive care unit)**
- **Survival of ICU patients with echocardiographically detectable cardiac pathologies (clinical parameters investigated during the stay in intensive care, Kaplan-Meier survival analysis)**
- **Sensitivities, specificities, positive predictive values, negative predictive values for the presence of cardiac pathologies detected by ECG and chest x-ray interpretation (correlation of ECG and chest x-ray interpretation conducted during day 1-3 in the intensive care unit with echocardiographic detectable cardiac pathologies conducted on the third day of the intensive care stay)**
- **Transthoracic image quality in ICU patients (evaluation on the third day in intensive care by transthoracic echocardiography)**
- **Prediction of cardiac pathologies by established ICU parameters (SAPS II; days in intensive care, etc.) [echocardiographic evaluation from the third day in intensive care and clinical parameters from the entire stay in the intensive care unit]**

Secondary Outcome

In addition to the primary endpoints the following secondary endpoint will be evaluated:

- **relevance and usefulness of the echocardiographic evaluation on the third day of the ICU stay determined by a questionnaire answered by the attending resident and consultant**

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 intensive care patients on their third day in the ICU

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

* 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.