

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

Trial Description

Title

Influence of risk factors and prevention with sodium bicarbonate on the incidence of acute kidney injury after cardiac surgery

Trial Acronym

AKI risk factors

URL of the trial

[---]*

Brief Summary in Lay Language

Prospective observational trial of the influence of pre- and intraoperative risk factors and sodium bicarbonate iv infusion on the incidence of AKI after on-pump cardiac surgery.

Brief Summary in Scientific Language

The data of this study resulted from a large observational trial of pre- and intraoperative risk factors of AKI after cardiac surgery. Influence of sodium bicarbonate iv infusion on the incidence of AKI after on-pump cardiac surgery.

Organizational Data

- DRKS-ID: **DRKS00007616**
- Date of Registration in DRKS: **2014/12/12**
- 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.: **21/6/09 , Ethik-Kommission der Medizinischen Fakultät der Georg-August-Universität Göttingen**

Secondary IDs



Health condition or Problem studied

- ICD10: **N17 - Acute renal failure**

Interventions/Observational Groups

- Arm 1: **Patient without acute kidney injury.**
Determination of preoperative risk factors of AKI according to Thakar et al. (2005) and intraoperative factors: CPB-time, aortic cross clamping time, free hemoglobin, blood transfusion, sodium bicarbonate iv infusion (according to standard operation procedure of the department 8,4% iv 0,15mmol/kg/BW/h, start after induction of anesthesia until 2 p.m. of the first postoperative day). Postoperative Evaluation of AKI according to AKIN-criteria.
- Arm 2: **patients with acute kidney injury.**
Determination of preoperative risk factors of AKI according to Thakar et al. (2005) and intraoperative factors: CPB-time, aortic cross clamping time, free hemoglobin, blood transfusion, sodium bicarbonate iv infusion (according to standard operation procedure of the department (8,4% iv 0,15mmol/kg/BW/h, start after induction of anesthesia until 2 p.m. of the first postoperative day). Postoperative Evaluation of AKI according to AKIN-criteria

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

AKI defined according to AKIN-Criteria

Secondary Outcome

length of stay, in-hospital mortality

Countries of recruitment



- **DE Germany**

Locations of Recruitment

- University Medical Center **Zentrum Anästhesie, Rettungs- und Intensivmedizin, Göttingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/08/25**
- Target Sample Size: **1000**
- 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

on-pump cardiac surgery

Exclusion criteria

preoperative renal replacement therapy

Addresses

- **Primary Sponsor**

**Universitätsmedizin Göttingen
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37099 Göttingen
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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): **2011/04/01**

Trial Publications, Results and other documents

- Paper [---]*

* 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.