# Trial Description

## Title

**Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury**

## Trial Acronym

**Sapphire AST-111**

## URL of the trial

**[---]***

## Brief Summary in Lay Language

**The objective of this multicenter prospective cohort study is to collect blood and urine samples to identify and validate novel biomarkers from acutely ill patients for the early detection and risk assessment of acute kidney injury (AKI). As the study is observational there will be no impact on the medical management of the patient with minimum risk.**

**This study will cover a period of about 8 months, approximately 1,000 adult ICU patients at risk for acute kidney injury at ~30 clinical sites. The study targets patients who do not have known moderate or severe acute kidney injury at enrollment, are expected to be in the ICU for at least 48 hours with a urinary catheter as standard care and who have hemodynamic and/or respiratory dysfunction.**

**Renal function will be classified based on serum creatinine and urine output. Of primary interest are biomarkers for the risk assessment for development of moderate or severe acut kidney disease 24-48 hours prior to significant changes in serum creatinine levels and urine output. Secondary outcomes of interest include need for dialysis, mortality, ICU and hospital length of stay as well as longer-term outcomes such as recovery from acute kidney injury or development of chronic kidney disease.**

**Data available in the patient's hospital record as part of standard care will be recorded in the study CRFs. This includes serum creatinine results, urine output data, results of relevant routine laboratory tests, results from renal biopsy or renal ultrasound. ICU and hospital length of stay, dialysis and. At 1, 3 and 9 months health status will also be assessed by phone call.**

## Brief Summary in Scientific Language

**The purpose of this study is to collect blood and urine samples that may help identify and validate biomarkers for the early detection and risk assessment of**

**acute kidney injury (AKI).**

**For brief summary please see above.**

## Organizational Data

- DRKS-ID: **DRKS00003499**
- Date of Registration in DRKS: **2012/05/18**
- Date of Registration in Partner Registry or other Primary Registry: **2010/09/23**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **151/10 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

## Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2010-023138-22**
- Primary Registry-ID: **NCT01209169 (ClinicalTrials.gov)**

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Patients in a critical condition caused by polytrauma, surgery, sepsis or similar events are enrolled in this study. Stratification is not applicable. It is essential that the patients show the SOFA-score described above within 24 hours prior to enrolment and the kidneys only show risk of injury at the most. The fluid in and output needs to be closely monitored for up to the next 7 days but for a minimum of 48 hours in ICU and the samples are to be taken within a set time window. Additional health data and acute conditions are recorded as well beyond these 7 days up to 30 days or discharge (whichever comes first). During follow-up at months 1, 3, and 9 months after day 7 the patients will be contacted again to document their health condition, to possibly complete a quality of life questionnaire and if applicable to collect another blood sample.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**

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Study Type Non-Interventional: **Other**

- 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): **N/A**

### Primary Outcome

**Of primary interest are biomarkers for the risk assessment for development of moderate or severe acute kidney injury (AKI) (RIFLE-I or RIFLE-F; AKIN 2 or AKIN 3), 24-48 hours prior to significant changes in serum creatinine or urine output.**

### Secondary Outcome

**Secondary outcomes of interest include need for dialysis, mortality, ICU and hospital length of stay as well as longer-term outcomes such as recovery from AKI or development of CKD.**

## Countries of recruitment

- US **United States**
- UK **United Kingdom**
- SE **Sweden**
- AT **Austria**
- CA **Canada**
- FR **France**
- ES **Spain**
- DE **Germany**
- BE **Belgium**

## Locations of Recruitment

- University Medical Center **Magdeburg**
- University Medical Center **Frankfurt a.M.**
- University Medical Center **Essen**
- University Medical Center **Aachen**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/02/28**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **21 Years**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Males and females 21 years of age or older;**

**Subjects enrolled (first sample collection) from ED or Floor admitted to the ICU within 24 hours of enrollment; Subjects enrolled from ICU admitted to the ICU within the 24 hours prior to enrollment; Expected to remain in the ICU for at least 48 hours after enrollment; Use of indwelling urinary catheter as standard care expected for at least 48 hours after enrollment; At least one of the following acute conditions within 24 hours prior to enrollment:**

**(Respiratory SOFA score of ≥ 2 (PaO2/FiO2 <300)and/or Cardiovascular SOFA score of ≥ 1 (MAP < 70 mm Hg and/or any vasopressor required).**

**Patient (or authorized representative) able and willing to provide written informed consent for study participation.**

### Exclusion criteria

**Special populations including women with known pregnancy, prisoners or institutionalized individuals;**
**Previous renal transplantation;**
**Known moderate to severe AKI prior to enrollment (e.g., RIFLE-I or RIFLE-F/ AKIN 2 or AKIN 3)**
**Already receiving dialysis (either acute or chronic) or in imminent need of dialysis at the time of enrollment; Known infection with human immunodeficiency virus**

**(HIV) or active hepatitis (acute or chronic);Patient meets any of the following:Active bleeding with an anticipated need for > 4 units PRBC;Hemoglobin < 7 g/dL;Any other condition that in the physician's opinion would contraindicate drawing serial blood samples for clinical study purposes.**

## Addresses

- **Primary Sponsor**

  **Astute Medical, Inc. VP, Clinical & Regulatory Strategy**
  **Ms. Ph.D. Karin Hughes**
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  **92121 San Diego**
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- **Contact for Scientific Queries**

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## Sources of Monetary or Material Support

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

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## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2012/12/23**

## Trial Publications, Results and other documents

- Further trial documents **Website**
- Paper **Discovery and validation of cell cycle arrest biomarkers in human acute kidney injury; Critical Care 2013, 17:R25 doi:10.1186/cc12503**

** 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.*