PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Regulation of L-Arginine Und Its Derivatives of Asymmetrical and Symmetrical Dimethylarginine and L-NG Monomethylarginine (ADMA/SDMA/L-NMMA) in Acute Kidney Injury and Correlation to Cardiac, Renal and Vascular Function and Mortality

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of the study is to determine the association between acute kidney injury and serum levels symmetrical and asymmetrical dimethylarginine (SDMA/ADMA) and their assumptive influence on mortality, renal function and on arterial stiffness.

Brief Summary in Scientific Language

Acute kidney injury (AKI) is a frequent complication with severe implications deteriorating overall prognosis. Nitric oxide (NO)-signal transduction plays an important role in mediating renal damage. NO is produced by NO-synthase (NOS) with L-arginine as its substrate. Endogenous L-Arginine derivatives, asymmetric and symmetric dimethylarginines (ADMA/SDMA), inhibit NO-production directly (AMDA) by blocking NOS activity or indirectly (SDMA) by blocking cellular L-Arginine uptake.

It is well known that SDMA and ADMA are markers of renal function (SDMA) and cardiovascular risk (ADMA/SDMA) in patients with chronic kidney disease (CKD). Moreover, ADMA and SDMA possibly even trigger cardiovascular risk in patients with CKD. However, there is only little information about the regulation and the influence of ADMA/SDMA in acute kidney

injury.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00006378**
- Date of Registration in DRKS: **2015/04/09**
- Date of Registration in Partner Registry or other Primary Registry: **2012/02/02**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01552525 (ClinicalTrials.gov)**
- Sponsor-ID: **91/10 (Wuerzburg University Hospital)**

Health condition or Problem studied

- Free text: **Acute Kidney Injury**
- ICD10: **N17 - Acute renal failure**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***

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- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Difference in serum ADMA level between acute kidney injury and renal recovery; time frame: participants will be followed from the time of recruitment to the end of hospital stay, an expected average of 2 weeks
- Difference in serum SDMA level between acute kidney injury and renal recovery; time frame: participants will be followed from the time of recruitment to the end of hospital stay, an expected average of 2 weeks

Secondary Outcome

- Associations between ADMA/SDMA serum level and all cause mortality; time frame: participants will be followed from the time of recruitment to the end of hospital stay, an expected average of 2 weeks
- Associations between ADMA/SDMA serum level and parameters of arterial stiffness; time frame: participants will be followed from the time of recruitment to the end of hospital stay, an expected average of 2 weeks; Parameters of arterial stiffness include augmentation index and pulse wave velocity
- Associations between ADMA/SDMA serum level and parameters of renal function; time frame: participants will be followed from the time of recruitment to the end of hospital stay, an expected average of 2 weeks; Parameters of renal function include serum creatinine and estimated Glomerular Filtration Rate (eGFR)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **University Hospital of Wuerzburg, Wuerzburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/01/31**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- acute kidney injury according to the definition of AKIN (Acute Kidney Injury Network)

- no started renal replacement therapy (e.g. dialysis)

Exclusion criteria

- dialysis or continuous venovenous hemofiltration before recruitment

- no recovery from kidney injury according to the definition of AKIN (Acute Kidney Injury Network)

- palliative care

- life expectancy is severely limited (< six months) due to preexisting malignancy or other disease

Addresses

- **Primary Sponsor**

  Wuerzburg University Hospital

Primary Sponsor

Wuerzburg University Hospital

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

Division of Nephrology Department of Medicine I University Hospital of Wuerzburg
Boris B Betz, Dr

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Public Queries**

Boris B Betz, Dr

Telephone: **+49 931 201 40715**
Fax: **[---]***
E-mail: **betz_b at medizin.uni-wuerzburg.de**
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Mehta RL, Kellum JA, Shah SV, Molitoris BA, Ronco C, Warnock DG, Levin A; Acute Kidney Injury Network. Acute Kidney Injury Network: report of an initiative to improve outcomes in acute kidney injury. Crit Care. 2007;11(2):R31.; 17331245**