Trial Description

Title

Effect of a preinterventional calorie restriction on renal function after contrast agent exposition in patients at risk.

Trial Acronym

CR_KMN

URL of the trial

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Brief Summary in Lay Language

In this study we investigate the impact of a calorie restriction on renal function.

**It is known that administration of a contrast agent may damage the kidney and lead to a loss of kidney function. Patients with risk factors such as Diabetes, chronic kidney disease ans several other disorders are at increased risk.
Until now, apart from volume administration, there is no known medication or procedure that might protect the kidney from this damage.**

A possible positive effect of a diet on renal function has been shown in several investigations on mammals. Apart from that, clinical trials have been performed, showing, that even before operations diets do not have a negative impact on the outcome

By conducting this trial, we want to investigate if a calorie restriction can protect the kidney from the negative influence of contrast agent

Brief Summary in Scientific Language

The contrast-induced nephropathy is a significant reason of the acute renal failure which is associated with a considerable gain of mortality. In view of the large number of daily conducted contrast agent investigations the contrast-induced nephropathy represents a particular medical and health economic challenge. None of the actual initiated preventive procedures presented a benefit in terms of a contrast-induced nephropathy prevention. The only approved assured procedure is currently the peri-interventional fluid administration. An ischemia of particular hypoxia sensitive tubular regions is patho-physiological in the focus of the appearance of contrast-induced nephropathy. As displayed in animal experiments a short-term calorie restriction lead directly to biochemical and cellular adaption incident which caused a considerable increased resistence towards ischemic organ

damages.
This planned study shall analyze how the short-term pre-interventional calorie restriction can have a positive effect of the renal function after contrast agent exposition.

Organizational Data

- DRKS-ID: **DRKS00004361**
- Date of Registration in DRKS: **2013/04/23**
- Date of Registration in Partner Registry or other Primary Registry: **2013/06/13**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **13-017 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2012-003696-18**
- Primary Registry-ID: **NCT01879839 (ClinicalTrials.gov)**
- BfArM-No.: **4038890**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Intervention: Calorie Restriction to 60% of the calculated daily energy rate**
- Arm 2: **Control group: Ad libitum alimentation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Control group receives no treatment**

- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Analysis of the increment of serum creatinine 48h after the onset of coronary intervention (contrast agent exposition).

Secondary Outcome

Analysis of the increment of serum creatinine 24h after the onset of coronary intervention (contrast agent exposition); Neutrophil gelatinase-associated lipocalin (NGAL in µg/l) in urine 24h after the onset of coronary intervention (contrast agent exposition); Cystatin C in plasma (mg/l) 24h after the onset of coronary intervention (contrast agent exposition)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik II für Innere Medizin Nephrologie, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/07/10**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Monocenter trial**
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Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2013/07/10**

Target Sample Size: **80**

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

1. men and women 18 years of age or older
2. caucasian origin
3. scheduled coronary angiography
4. indication for coronary angiography is determined by the referring physician
5. Patient and/or legal guardian must be willing and able to give written informed consent
6. at least one of the following risk factors:
•serumkreatinine > 1,1 mg/dl in male patients or serumkreatinin > 0,9 mg/dl in female patients
•Diabetes mellitus
•peripher arteriovascular disease
•heartfailure with NYHA 3-4 or ejection fraction ≤ 50%
•age over 70 years

Exclusion criteria

1. End-stage renal disease (patient on dialysis);
2. Indwelling kidney transplant;
3. Malnutrition (BMI < 18,5 kg/m2);
4. Body weight < 46 kg in male, < 51 kg in female;
5. BMI > 35 kg/m2 or body weight > 120 kg;
6. diet within the previous 4 weeks;
7. Inappetence ;
8. Weight loss > 1 kg within the previous 2 weeks, if not explained by use of diuretics;
09. Consuming underlying disease;
10. Uncontrolled local or systemic infection;
11. Contraindication for enteral nutrition;
12. Known allergy against or incompatibility with ingredients of the employed formula-diet;
13. Pregnancy or breast feeding;
14. Participation in other interventional clinical trials;
15. Missing safe method of contraception or missing occurence of menopause (in female);

16. Professional or private relationship between subject and the investigators or dependence on the investigators;
17. Placement in an institution based on official orders.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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  53175 Bonn
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  Telephone: **[---]***
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  E-mail: **[---]***
  URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/10/07**

Trial Publications, Results and other documents

- Trial results **CR_KMN_Abschlussbericht**

** 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.*