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

Trial Description

Title

Pausing the barostimulation to test its efficacy in therapy resistant hypertension

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

With this project we aim to further prove the efficacy of the barostimulation therapy in therapy resistent hypertension. Barostimulation is a device-based therapie, where a pacemaker like device triggers a reflex which reduces blood pressure. This therapy is approved for patients with blood pressure above 140/90 mmHg in spite of ongoing therapy with at least 3 antihypertensive drugs. At the University Clinic of Cologne we already treat 35 patientes with therapy resistant hypertension with this device. In this project we plan to pause the barostimulation therapy for 4 weeks before operative device replacement (because of a low battery Status) in a crossover design.
With this we aim to gain knowledge about the individual and general therapy response and efficacy of the barostimulation therapy. If we cannot prove its efficacy in an individual patient the device will not be replaced but explanted if that is the patient's wish.
We hypothesize that we can prove that barostimulation is an effective therapy in resistant Hypertension.

Brief Summary in Scientific Language

With this project we aim to further prove the efficacy of the barostimulation therapy in therapy resistent hypertension. Barostimulation is a device-based therapie which activates the baroreflex via electrical stimulation of the carotid sinus. An electrical pulse generator is implanted below the clavicle and one small electrode ist connected to the artery wall near the carotid sinus. This therapy is approved for patients with blood pressure above 140/90 mmHg in spite of ongoing therapy with at least 3 antihypertensive drugs. At the University Clinic of Cologne we already treat 35 patientes with therapy resistant hypertension with this device. In this project we plan to pause the barostimulation therapy for 4 weeks before operative device replacement because of a low battery status. With this we aim to gain knowledge about the individual and general therapy response and efficacy of the barostimulation therapy. If we cannot prove its efficacy in an individual patient the device will not be replaced but explanted if that is the patient's wish.

Organizational Data

- DRKS-ID: **DRKS00010221**
- Date of Registration in DRKS: **2017/07/18**
- 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.: **16-132 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- Free text: **Therapy resistant hypertension**
- ICD10: **I10 - Essential (primary) hypertension**

Interventions/Observational Groups

- Arm 1: **Pausing the barostimulation therapy for the first 4 weeks of the trial, continuing the barostimulation therapy for the second 4 weeks of the trial**
- Arm 2: **Continuing the barostimulation therapy in the first 4 weeks of the trial, pausing the barostimulation therapy for the second 4 weeks of the trial**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**

Study Type: **Interventional**

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

Allocation: **Randomized controlled trial**

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

Who is blinded: **patient/subject, investigator/therapist**

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Crossover**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

relevant rise of blood pressure after 1 month pause of barostimulation therapy measured in telemetric and/or office blood pressure

Secondary Outcome

/

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Kardiologie, Köln**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/12/06**
- Target Sample Size: **35**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- therapy resistant hypertension where secondary causes of hypertension have been excluded
- barostimulation with low battery Status
- written consent to participate in the trial after the patient has been informed of the content of the trial in writing and in person

Exclusion criteria

- battery replacement of the barostimulation device not possible at the moment because of medical or other reasons
- therapeutic effect of the barostimulation therapy has already been proven in this patient

Addresses

- **Primary Sponsor**

  Universitätsklinik Köln Kardiologie
  Mr. PD Dr. med Marcel Halbach
  Kerpener Str. 62
  50937 Köln
  Germany

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

- **Contact for Scientific Queries**

  Universitätsklinik Köln Kardiologie
  Ms. Dr. med Lisa Ulbrich
  Kerpener Str. 62
  50937 Köln
  Germany

  Telephone: **0221 / 478 97177**
  Fax: **[---]***
  E-mail: **lisa.ulbrich at uk-koeln.de**
  URL: **[---]***

- **Contact for Public Queries**

  Universitätsklinik Köln Kardiologie

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Universitätsklinik Köln Kardiologie
Ms. Dr. med Lisa Ulbrich
Kerpener Str. 62
50937 Köln
Germany

Telephone: **0221 / 478 97177**
Fax: **[---]***
E-mail: **lisa.ulbrich at uk-koeln.de**
URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Universitätsklinikum Köln
Kerpener Str. 62
50924 Köln
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.medizin.uni-koeln.de**

Status

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

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.*