Trial Description

Title

Chemical renal denervation for the treatment of resistant hypertension

Trial Acronym

CRASH

URL of the trial

[---]*

Brief Summary in Lay Language

Decrease of average systolic ambulatory blood pressure after CT-guided ethanol renal denervation compared to a control group with sham intervention. Both study groups receive a standardized antihypertensive medication 4 weeks prior to inclusion in the study. No change in the standardized anti-hypertensive medication is allowed during the study, medication optimization within the framework of standard treatment is allowed during the duration of the study. Planned study duration is 6 months.

Brief Summary in Scientific Language

Decrease of the mean systolic ABP after CT-guided ethanol RSD compared to a control group undergoing sham procedure 6 months after intervention. Both arms receive standardized antihypertensive medication for 4 weeks before randomization. No change of standard medication other than dose adjustment for 6 months.

Organizational Data

- DRKS-ID: **DRKS00008746**
- Date of Registration in DRKS: **2019/06/19**
- 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.: **18-599 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

- Other Secondary-ID: **LMU-RAD00009 (interne Studien-ID LMU Radiologie)**

Health condition or Problem studied

- ICD10: **I10.9 - [generalization I10: Essential (primary) hypertension]**

Interventions/Observational Groups

- Arm 1: **Therapy Arm:**
  24-hour blood pressure measurements and automated office-blood-pressure (RR) measurements are taken before the intervention (baseline).
  After patient approval, therapy is performed by image-guided instillation of a neurolytic near the renal arteries.

  Follow-up with duplex sonography, MRI incl. MR angiography or detection of further complications are recorded in the high-pressure nephrology or Department of radiology
  Immediately after the intervention and after 3, 6, 12, 18 and 24 months, the blood pressure is measured.
- Arm 2: **SHAM Arm:**
  24-hour blood pressure measurements and automated office-blood-pressure (RR) measurements are taken before the intervention (baseline).
  After patient consent, therapy is performed by Sham therapy near the renal arteries.

  Follow-up with duplex sonography, MRI incl. MR angiography or detection of further complications are recorded in the high-pressure nephrology or Department of radiology
  Immediately after the intervention and after 3, 6, 12, 18 and 24 months, the blood pressure is measured.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver, assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

The procedure leads to a permanent lowering of blood pressure compared to the

control group (state of the art antihypertensive medication plus sham treatment).

Secondary Outcome

• Permanent reduction of antihypertensive medication in patients with refractory hypertension compared to sham control
• Compared to catheter-guided radiofrequency ablation, the procedure is simpler, faster, less expensive, and feasible for patients with a contraindication to RFA.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik und Poliklinik für Radiologie, München**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/28**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

• Patient with therapy-resistant type. Hypertonicity (syst. RR> 140 mmHg despite optimized therapy with ≥ 3 antihypertensive drugs of different classes - state of the art over 3 months),
• Diagnosis of the therapy-resistant type. Hypertension by a specialist in nephrology / high-pressure ambulance takes place incl. Advice on all alternative therapy methods
• GFR> 45 ml / min / 1.73 m²
Pat. With refractory hypertension at Z.n. ineffective catheter-directed RDN

Exclusion criteria

• patients with secondary hypertension (e.g., renoparenchymatous hypertension, NAST, primary hyperaldosteronism, pheochromocytoma, sleep apnea syndrome)
• Stenosing heart valve disease
• Z.n. Myocardial infarction, unstable angina pectoris, cerebrovascular event within the last 6 months prior to enrollment

Addresses

■ **Primary Sponsor**

Klinikum der Universität München, Campus Großhadern
Marchioninistraße 15
81377 München
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.klinikum.uni-muenchen.de**

■ **Contact for Scientific Queries**

Klinik und Poliklinik für Radiologie Klinikum der Universität München Campus Großhadern
Mr. Prof. Florian Streitparth
Marchioninistr. 15
81377 München
Germany

Telephone: **(089) 4400-4400 72750**
Fax: **(089) 4400-4400 76648**
E-mail: **Florian.Streitparth at med.uni-muenchen.de**
URL: **http://intranet.klinikum.uni-muenchen.de**

■ **Contact for Public Queries**

Klinik und Poliklinik für Radiologie Klinikum der Universität München Campus Großhadern
Ms. Christel Besseler
Marchioninistr. 15
81377 München
Germany

Telephone: **(089) 4400-73647**
Fax: **(089) 4400-76648**
E-mail: **christel.besseler at med.uni-muenchen.de**
URL: **http://intranet.klinikum.uni-muenchen.de**

■ **Collaborator, Other Address**

Medizinische Klinik und Poliklinik IVKlinikum der Universität München Campus Großhadern
Mr. Prof. Michael Fischereder

Collaborator, Other Address

Medizinische Klinik und Poliklinik IVKlinikum der Universität München Campus Großhadern
Mr. Prof. Michael Fischereder
Marchioninistr. 15
81377 München
Germany

Telephone: **089/4400-72211**
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.klinikum.uni-muenchen.de/Medizinische-Klinik-und-Poliklinik-IV/de**

- **Contact for Scientific Queries**

Klinik und Poliklinik für Radiologie Klinikum der Universität München Campus Großhadern
Mr. Dr. Daniel Puhr-Westerheide
Marchioninistr. 15
81377 München
Germany

Telephone: **+49 89 440073660**
Fax: **+49 89 440076648**
E-mail: **Daniel.Puhr-Westerheide at med.uni-muenchen.de**
URL: **http://intranet.klinikum.uni-muenchen.de**

Sources of Monetary or Material Support

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

Klinik und Poliklinik für Radiologie Klinikum der Universität München Campus Großhadern
Mr. Prof. Jens Ricke
Marchioninistr. 15
81377 München
Germany

Telephone: **(089) 4400-4400 72750**
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
-

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.*