

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

## Trial Description

### Title

**Development and validation of magnet resonance elastography of the aorta for assessment of the central cardiovascular system**

### Trial Acronym

**MREAo**

### URL of the trial

<http://elastography.de>

### Brief Summary in Lay Language

**Cardiovascular diseases are one of the most common causes of serious illness in the Western world. In this context, increasing vascular stiffness, which is aggravated by arterial hypertension, is an important factor in the pathogenesis and deterioration of cardiovascular diseases. The increase in stiffness of large central arteries has serious consequences for the human body, since it i.a. reduces bloodflow in the coronary arteries and thus impairs cardiac output. The aim of this study is to further develop and validate magnet resonance elastography regarding a quantification of the stiffness of the aorta in order to detect an end organ damage of the large arteries at an early stage.**

### Brief Summary in Scientific Language

**The aim of this study is the implementation and validation of MR elastography of the aorta for the purpose of spatially resolved quantification of vascular stiffness. Using MR elastography, a possible end organ damage of the aorta may be quantified directly by means of mechanical characteristics.**

## Organizational Data

- DRKS-ID: **DRKS00013598**
- Date of Registration in DRKS: **2018/03/07**
- 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.: **EA4/085/14 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**



## Secondary IDs

## Health condition or Problem studied

- ICD10: **I10-I15 - Hypertensive diseases**
- ICD10: **I70-I79 - Diseases of arteries, arterioles and capillaries**

## Interventions/Observational Groups

- Arm 1: **Patients with diagnosed arterial hypertension. Patients undergo measurements of pulse wave velocity and peripheral blood pressure as well as magnet resonance elastography of the aorta.**
- Arm 2: **Healthy volunteers. Volunteers undergo measurements of pulse wave velocity and peripheral blood pressure as well as magnet resonance elastography of the aorta.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]\***
- Who is blinded: **[---]\***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**The primary outcome is the successful measurement of regional aortic stiffness in healthy volunteers and patients with the help of magnet resonance elastography. This is a feasibility study with the purpose of introducing a new diagnostic parameter.**

## Secondary Outcome

**Derivation of diagnostic parameters. Comparison of derived parameters with established methods.**

**Derivation of diagnostic parameters. Comparison of derived parameters with established methods.**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Medical Center **Charité-Universitätsmedizin (Campus Benjamin Franklin, Campus Charité Mitte), Berlin**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/01**
- Target Sample Size: **200**
- 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

**History of arterial hypertension or healthy volunteers**

### Exclusion criteria

**pregnancy, acute myocardial infarction or stroke within 14 days before the examination**

## Addresses

- **Primary Sponsor**

**Klinik und Hochschulambulanz für Radiologie, Campus Benjamin Franklin,**

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**Primary Sponsor**

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■ **Contact for Scientific Queries**

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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.)**

**Deutsche Forschungsgemeinschaft**

**Kennedyallee 40**

**53175 Bonn**

**Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.dfg.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.