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

Trial Description

Title

Development and validation of ultrasound elastography of the aorta for assessment of the central cardiovascular system

Trial Acronym

USEAo

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 cardiovasculars 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 ultrasound 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 ultrasound elastography (USE) of the aorta for the purpose of spatially resolved quantification of vascular stiffness. With USE, a possible end organ damage of the aorta may be quantified directly by means of mechanical characteristics.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013568**
- 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.: **EA1/056/16 , 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 ultrasound elastography of the aorta.**
- Arm 2: **Healthy volunteers. Volunteers undergo measurements of pulse wave velocity and peripheral blood pressure as well as ultrasound 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 ultrasound elastograpyh. 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.

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: **99 Years**

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, Charité-Universitätsmedizin Berlin
Mr. Priv.-Doz. Dr. med. Thomas Elgeti
Hindenburgdamm 30
12203 Berlin
Germany

Telephone: **030450627773**
Fax: **[---]***
E-mail: **thomas.elgeti at charite.de**
URL: **http://radiologie.charite.de**

■ **Contact for Scientific Queries**

Klinik und Hochschulambulanz für Radiologie, Campus Benjamin Franklin, Charité-Universitätsmedizin Berlin
Mr. Priv.-Doz. Dr. med. Thomas Elgeti
Hindenburgdamm 30
12203 Berlin
Germany

Telephone: **030450627773**
Fax: **[---]***
E-mail: **thomas.elgeti at charite.de**
URL: **http://radiologie.charite.de**

■ **Contact for Public Queries**

Klinik und Hochschulambulanz für Radiologie, Campus Benjamin Franklin, Charité-Universitätsmedizin Berlin
Mr. Dr. med. Lars-Arne Schaafs
Hindenburgdamm 30
12203 Berlin
Germany

Telephone: **004930450627796**
Fax: **[---]***
E-mail: **lars-arne.schaafs at charite.de**
URL: **http://radiologie.charite.de**

■ **Collaborator, Other Address**

Institut für Radiologie, Campus Charité Mitte, Charité-Universitätsmedizin Berlin
Mr. Prof. Dr. rer. nat. Ingolf Sack
Charitéplatz 1
10117 Berlin
Germany

Collaborator, Other Address

Institut für Radiologie, Campus Charité Mitte, Charité-Universitätsmedizin Berlin
Mr. Prof. Dr. rer. nat. Ingolf Sack
Charitéplatz 1
10117 Berlin
Germany

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

Sources of Monetary or Material Support

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

Charité Campus Benjamin Franklin
Hindenburgdamm 30
12203 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.charite.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.*