

Trial Description

Title

Aortic plaques as a source of stroke - MRI based morphological and functional analysis of the aorta.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Aortic atheroma are known to be a relevant source of stroke for 20 years. However, it is unclear why they occur in specific areas of the aorta, which hemodynamic parameters have influence on their formation and progression, and if plaques of the descending aorta cause brain infarction due to diastolic blood flow reversal. This project aims to apply Magnetic Resonance Imaging (MRI) for detection and evaluation of aortic atheroma in 3D. Furthermore, functional MRI will be performed to visualize individual blood flow and evaluate the risk of embolization to the brain. All experiments will be performed on stroke patients and controls.

Brief Summary in Scientific Language

Aortic plaques are known to be a relevant source of stroke for 20 years. However, it is unclear why they occur on predilection sites, which hemodynamic parameters have influence on their formation, progression, and rupture, and if plaques of the descending aorta cause brain infarction due to diastolic blood flow reversal. This project aims to apply the combination of functional MRI with modern image analysis methods for the evaluation of the risk of infarction due to plaques of the descending aorta on a representative cohort of stroke patients and controls. Atheroma of the aorta are detected and characterized concerning their composition by using a multi-parametric 3D/4D MRI protocol. Subsequently, the location of plaques can be correlated with local wall shear stress and elasticity of the aorta, which are acquired quantitatively by 4D flow MRI. It should be determined to what extent altered local hemodynamics are a predictor for the occurrence and rupture of vulnerable plaques. Furthermore, individual embolization pathways can be visualized and the connection between aortic atheroma and the location of cerebral infarction should be quantified using connectivity maps. Thus, the relevance of the so far neglected but numerous plaques of the descending aorta as a high-risk source of stroke can be evaluated resulting in an optimized secondary prevention in the future.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00006234**
- Date of Registration in DRKS: **2014/06/11**
- 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.: **227/14** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1157-8605**

Health condition or Problem studied

- ICD10: **I63 - Cerebral infarction**

Interventions/Observational Groups

- Arm 1: **Stroke patients undergo aortic MRI (3D multicontrast MRI and 4D flow MRI) for the detection and evaluation of atherosclerotic plaques and analysis of blood flow.**
- Arm 2: **Ophthalmic patients (controls) undergo aortic MRI (3D multicontrast MRI and 4D flow MRI) for the detection and evaluation of atherosclerotic plaques and analysis of blood flow.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Diagnostic**
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Non-randomized controlled trial**

Blinding: [---]*

Who is blinded: [---]*

Control: **Other**

Purpose: **Diagnostic**

Assignment: **Other**

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

Primary Outcome

Quantitative analysis of the frequency of retrograde embolization from complex plaques of the descending aorta into the supra-aortic arteries in patients with undetermined and determined stroke etiology and controls.

Secondary Outcome

1. Quantification of plaque morphology using 3D multicontrast MRI. 2. In stroke patients: Testing the hypothesis that plaques occur primarily on locations with critically altered WSS and reduced PWV. 3. Correlation of aortic elasticity and flow reversal in the descending aorta.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätskliniken für Neurologie und Augenheilkunde, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/09/25**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Stroke patients: male and female, >49 years of age, acute stroke, cryptogenic stroke etiology after routine diagnostics (without TEE), visible ischemic lesion on cerebral imaging. 2. Control patients: male and female, >49 years of age, no history of cerebral or retinal ischemia.

Exclusion criteria

Contraindications for MRI (ferromagnetic prosthesis, cardiac pacemaker, implantable cardioverter defibrillator, insulin pump, large-scale tattoos with metalliferous pigment, artificial heart valves, pregnancy, cochlea implant, copper-bearing contraceptive coil, non-removable piercings, shell splinters or other metallic material), cardiac arrhythmias, bad general condition, no informed consent obtainable, strong claustrophobia, body weight over 130kg, refusal to participate in the study

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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■ **Collaborator, Other Address**

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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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URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/01/31**

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.