



Trial Description

Title

Influence Of Circulating Microvesicles On Vascular Inflammation

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

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Brief Summary in Scientific Language

Circulating microvesicles are a means of intercellular and inter-organ-communication even across large distances (e.g. heart-brain). In this study we want to investigate the characteristics of secreted microvesicles of circulating leukocytes in patients with atherosclerosis compared to healthy subjects.

Organizational Data

- DRKS-ID: **DRKS00009324**
- Date of Registration in DRKS: **2015/09/07**
- 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.: **EA2/059/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **I25.1 - Atherosclerotic heart disease**
- ICD10: **I70.2 - Atherosclerosis of arteries of extremities**

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Interventions/Observational Groups

- Arm 1: **Healthy volunteers: one-time blood draw, review of medical history**
- Arm 2: **Patients with coronary artery disease: one-time blood draw, review of medical history**
- Arm 3: **Patients with peripheral artery occlusive disease: one-time blood draw, review of medical history**

Characteristics

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

Primary Outcome

Microvesicle secretion profiles of different circulating leukocytes in healthy subjects and patients with coronary artery disease or peripheral artery occlusive disease

Secondary Outcome

Microvesicle function in different leukocyte populations in healthy subjects and patients with coronary artery disease or peripheral artery occlusive disease

Countries of recruitment

- **DE Germany**

Locations of Recruitment



- University Medical Center **Klinik für Kardiologie, Berlin**
- Doctor's Practice **Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/26**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

1. **in all groups age between 30 and 75 years**
 2. **in all groups male and female subjects**
- Age and sex should be homogenously distributed among study arms**
Group 1: healthy volunteers (i.e. no known cardiac disease, no family history)
Group 2: patients with stable coronary artery disease
Groups 3: patients with peripheral artery occlusive disease

Exclusion criteria

1. **pregnancy**
2. **renal failure (creatinin >265 umol)**
3. **liver failure**
4. **disease of the hematopoetic system**
5. **malignancy within the past 5 years (without evidence of relapse at time of inclusion)**
6. **acute or chronic inflammation**
7. **acute vascular event (e.g. myocardial infarction, stroke, pulmonary or systemic embolism) within the last year**
8. **inability to give informed consent**
9. **solid organ transplantation in history**
10. **acute shock**
11. **metabolic diseases including hereditary lipometabolic diseases and diabetes**

Addresses

- **Primary Sponsor**

Charité Universitätsmedizin Berlin Klinik für Kardiologie Campus Benjamin Franklin



Primary Sponsor

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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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Oudenarder Str. 16
13347 Berlin

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URL: [---]*

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.