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

Trial Description

Title

Biomarkers in Cardiology
BIC-1

Trial Acronym

BIC-1

URL of the trial

[---]*

Brief Summary in Lay Language

We want to establish a database with blood samples of healthy patients (BIC-1) as well as blood samples of patients with functional heart disorder (BIC-2). We will use those blood samples to find new biomarkers, like enzymes and messengers, and to figure out, if those biomarkers can help to advance risk analysis, diagnostic and hence also therapy of chronical heart diseases (cardiac insufficiency and cardiac infarction).
BIC-1 involves the collection of blood samples and data of 300 supposedly healthy Charité members of staff.

Brief Summary in Scientific Language

Primary objecitve of this study is the establishment of a database with blood samples from healthy patients (BIC-1) as well as patients of the emergency department with the cardinal symptoms of cardiological diseases: dyspnea and chest pain (BIC-2). Those blood samples will be analyzed to identify and evaluate new relevant biomarkers for risk analysis and diagnostic in cardiology.
Beneath others we will evaluate the following biomarkers:
Myoeloperoxidaxe, Plexental Growth Factor (PlGF), whole blood choline, hight sensitivity Troponine I.

Organizational Data

- DRKS-ID: **DRKS00000310**
- Date of Registration in DRKS: **2011/03/23**
- 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.: **EA2/030/07 , Ethik-Kommission der Charité -**

DRKS-ID: **DRKS00000310**
Date of Registration in DRKS: **2011/03/23**
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**
Universitätsmedizin Berlin-

Secondary IDs

- Universal Trial Number (UTN): **U1111-1119-7510**

Health condition or Problem studied

- ICD10: **I21 - Acute myocardial infarction**
- ICD10: **I50 - Heart failure**

Interventions/Observational Groups

- Arm 1: **Blood draw (50 mL), vital signs, assessment cardiovascular risk factors**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

/

/

Secondary Outcome

/

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/06/06**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

Patient full of age, healthy and able to sign informing consent

Exclusion criteria

- cardiovacular and metabolic diseases
- no adequate employment agreement (e.g. trainee, student)
- dependency from director of studies
- Hospitalization according to official or judicial order

Addresses

■ **Primary Sponsor**

Charité Berlin, Arbeitsbereich Notfallmedizin CVK und CCM, Medizinische Klinik m.S. Kardiologie
Mr. Prof. Martin Möckel
Augustenburger Platz 1
13353 Berlin
Germany

Telephone: **0049 (0)30 450 553472**
Fax: **0049 (0)30 450 553927**
E-mail: **martin.moeckel at charite.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Charité Berlin
Medizinische Klinik m.S. Kardiologie
Ms. Dr. Julia Searle
Augustenburger Platz 1
13353 Berlin
Germany

Telephone: **0049 (0)30 450 553307**
Fax: **0049 (0)30 450 7 553307**
E-mail: **julia.searle at charite.de**
URL: **[---]***

■ **Contact for Public Queries**

Charité
Campus Virchow Klinikum
Medizinische Klinik m. S. Kardiologie
Internistische Notaufnahme
Ms. Dr. med. Julia Searle
Augustenburger Platz 1
13353 Berlin
Germany

Telephone: **030-450-665-406**
Fax: **030-450-553-319**
E-mail: **julia.searle at charite.de**
URL: **http://www.charite.de/kardiologie/**

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Abbott Deutschland

Commercial (pharmaceutical industry, medical engineering industry, etc.)

Abbott Deutschland
Max-Planck-Ring 2
65205 Wies-baden
Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2007/11/29**

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.*