

Trial Description

Title

DZHK Translational Registry for Cardiomyopathies

Trial Acronym

TORCH

URL of the trial

<http://dzhk.de/forschung/klinische-forschung/aktuelle-studien/>

Brief Summary in Lay Language

Cardiomyopathies are severe hereditary or inflammatory heart diseases resulting from viral infections (Kühl et al., 2012; Cooper et al., 2009). Patients with cardiomyopathy require heart transplantation due to poor prognosis under conservative therapy (Kühl et al., 2012). Basic research on cardiomyopathies is important to improve the prognosis of these cardiomyopathy patients. The aim of the registry is to generate research results that can ultimately be applied in clinical routine care.

In the German Center for Cardiovascular Research (DZHK) one of the funded projects is the 'Translational Registry for Cardiomyopathies' (acronym: TORCH). In the multicenter registry TORCH cardiomyopathy patients are recruited. Their clinical phenotypes are determined and biomaterials blood and urine are collected. Additionally endomyocardial biopsies, which are not needed for diagnostics anymore, are provided. The assessment is performed at baseline and one-year follow up periods are planned.

The coordination center consists of the clinical scientific center Heidelberg and the data and quality center Greifswald. Data storage of identifying data is located in the trusted third party Greifswald and the medical data (medical history, clinical findings, and laboratory data) in the data warehouse Goettingen. The project ethics in Munich is responsible for all ethical aspects of the trial.

Brief Summary in Scientific Language

Cardiomyopathy is a major reason for cardiac transplantations and cause of heart failure in young adults. Possible reasons are chronic inflammation processes and gene mutations as 1q32 (Schönberger et al., 2004) or the CSRP3 missense mutation for hypertrophic cardiomyopathy (Geier et al., 2008).

In the German Centre for Cardiovascular Research (DZHK) one of the funded projects is 'Translational Registry for Cardiomyopathies' (acronym: TORCH). In this multicenter registry cardiomyopathy patients are recruited in DZHK-centers and external partner sites and are phenotyped in detail for research on causes regarding various exposures and factors genetic material. The detailed phenotyping is based on exhaustive standardized medical history and specific clinical investigations in routine diagnostics (electrocardiogram and long-term electrocardiogram, spiroergometry, echocardiography, six minute walk test, laboratory diagnostics, the determination of the vital status, and on clinical

indication magnetic resonance imaging and x-ray thorax). Additionally, patients are asked to complete a questionnaire of quality of life (Minnesota Living with Heart Failure questionnaire). Patients with medically depression are requested to complete a questionnaire of depression (Patient Health Questionnaire or others). The aims of the registry are the identification and recruitment of patients for other basic science as well as clinical studies and the research results are transferred in clinical routine care (translation).

The biomaterials whole blood and blood components, urine, and endomyocardial biopsies, which are not used for diagnostics, are stored in federated biorepository of TORCH partner sites. The biobank is established for detailed molecular analyses to research on the pathogenesis of cardiomyopathies. Genetic and epigenetic analyses based on extracted DNA and RNA are planned.

The coordination center consists of the clinical scientific center Heidelberg and the data and quality center Greifswald. The data entry is performed in the recruiting study centers and restricted to authorized clinical staff. The data of the included patients are managed by the central data management (CDM) consisting of the trusted third party Greifswald for identifying data, the data warehouse Goettingen for medical data (medical history, clinical findings, and laboratory data), and the IT management and laboratory system (ITLab) in Berlin. The ITLab is responsible for the initiation to the central laboratory information and management system (LIMS). The establishment of an image data management system (IDMS) of the DZHK is planned. The project ethics in Munich is responsible for all ethical aspects of the informed consent and supports the study centers at the local ethic committees.

Organizational Data

- DRKS-ID: **DRKS00008017**
- Date of Registration in DRKS: **2015/04/22**
- Date of Registration in Partner Registry or other Primary Registry: **2014/07/08**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-344/2014 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

- Primary Registry-ID: **NCT02187263 (ClinicalTrials.gov)**

Health condition or Problem studied

- ICD10: **E85 - Amyloidosis**
- ICD10: **I40 - Acute myocarditis**
- ICD10: **I42 - Cardiomyopathy**

Interventions/Observational Groups

- Arm 1: **In this multicenter registry cardiomyopathy patients are recruited in DZHK-centers and external partner sites and are phenotyped in detail for research on causes regarding various exposures and factors genetic material. The detailed phenotyping is based on exhaustive standardized medical history and specific clinical investigations in routine diagnostics (electrocardiogram and long-term electrocardiogram, spiroergometry, echocardiography, six minute walk test, laboratory diagnostics, the determination of the vital status, and on clinical indication magnetic resonance imaging and x-ray thorax). Additionally, patients are asked to complete a questionnaire of quality of life (Minnesota Living with Heart Failure questionnaire). Patients with medically depression are requested to complete a questionnaire of depression (Patient Health Questionnaire or others). The biomaterials whole blood and blood components, urine, and endomyocardial biopsies, which are not used for diagnostics, are stored in federated biorepository of TORCH partner sites.**

Characteristics

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

Primary Outcome

The primary endpoint in the TORCH-registry is all-cause death.

Secondary Outcome

The secondary outcomes are cardiovascular death, adequate ICD shock, survived sudden cardiac death, syncope or documented potentially life-threatening arrhythmia, cardiac transplantation, hospitalization due to the worsening of heart failure, and any non-elective cardiovascular hospitalization.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Kerkhoff Klinik, Bad Nauheim**
- **Charité Benjamin Franklin, Berlin**
- **Charité Campus Mitte, Berlin**
- **Virchow-Klinikum, Berlin**
- **Deutsches Herzzentrum - Kardiologie, Berlin**
- **Goethe-Universität, Frankfurt a.M.**
- **Universitätsmedizin, Greifswald**
- **Universitätsmedizin, Göttingen**
- **Universitätsklinikum, Hamburg-Eppendorf**
- **Universitätsklinikum, Heidelberg**
- **Universitätsklinikum, Schleswig-Holstein, Kiel**
- **Universitätsklinikum, Schleswig-Holstein, Lübeck**
- **Universitätsklinikum, Mannheim**
- **Deutsches Herzzentrum, München**
- **Medizinische Hochschule, Hannover**
- **Klinikum der Universität (LMU) - Innenstadt, München**
- **Klinikum rechts der Isar (TU), München**
- **Deutsches Herzzentrum - Herz, Thorax, Gefäße, Berlin**
- **University Medical Center Universitätsmedizin Mainz, Mainz**
- **University Medical Center Universitätsklinikum (LMU) München - Großhadern, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/01**
- Target Sample Size: **2300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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■ Minimum Age: **18 Years**

■ Maximum Age: **80 Years**

Additional Inclusion Criteria

- Hereditary and inflammatory dilated cardiomyopathy (DCM)
- Left ventricular dilatation (left ventricular end-diastolic diameter >117%)
- Left ventricular systolic dysfunction
- Hypertrophic cardiomyopathy (HCM)
- Left ventricular non-compaction (LVNC)
- Arrhythmogenic right ventricular cardiomyopathy (ARVC)
- Amyloidosis
- Myocarditis

Exclusion criteria

- <18 years, >80 years
- Other cardiac diseases:
- Severe arterial hypertension
- Primary pulmonary artery hypertension
- Chronic advanced non-cardiac diseases
- History of thorax radiation (life-long)
- Drug and alcohol abuse
- life expectancy <1 year due to non-cardiac diseases

Addresses

■ **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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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.