

Trial Description

Title

DMD-Carriers: Detection of Cardiomyopathy through Cardiac MRI and Echocardiography

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The group of carriers of the Duchenne Muscular Dystrophy has not been looked at in terms of a systematic work up of specific conditions concerning the heart. Having this in mind, we designed this study to obtain data regarding the heart and it's function in female carriers of Duchenne's Muscular Dystrophy.

We combine common standardised tests for mobility and strength in a regular physical examination with the use of standard procedures like ECG, 24h- ECG, 6 Minute Walk Test, an ultrasound of the heart and a magnetic resonance imaging (MRI) of the heart.

Inclusion criteria are positive genetic analysis for status of Duchenne's Dystrophy carrier, minimum age of 14 years.

We hope to identify structural and functional changes in the heart muscle of this group of people.

Brief Summary in Scientific Language

The study mentioned above is a monocentric, national, cross- sectional trial. Inclusion criteria are confirmed positive genetic analysis for carrier status of Duchenne Muscular Dystrophy in females, minimum age 14 years. The protocol includes a combination of both physical (e.g. Medical Research Council Muscular Test) and apparative examinations, such as ECG, Echocardiography and Cardiac MRI.

The main interest is to identify specific modifications in the myocardium of this population ad maybe develop a new approach to recommendations regarding a preventional cardiac follow up in Duchenne- carriers.

Organizational Data

- DRKS-ID: **DRKS00004539**
- Date of Registration in DRKS: **2012/11/30**
- 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**



DRKS-ID: **DRKS00004539**

Date of Registration in DRKS: **2012/11/30**

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.: **12-5117-BO , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- Free text: **Carrier of Duchenne Muscular Dystrophy**
- ICD10: **I42.9 - Cardiomyopathy, unspecified**

Interventions/Observational Groups

- Arm 1: **Following the protocol, the physical exam is structured by a form documenting standardised tests like e.g. MRC muscular functional test. The apparative diagnostics include ECG, 24ECG, 6 Minute Walk Test, Echocardiography and Cardiac MRI.**

Characteristics

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



Primary Outcome

Identification of Duchenne carriers´ specific changes/abnormalities in Cardiac MRI and echocardiography.

Secondary Outcome

Development of SOPs regarding the tested methods in this group of people, using the data from this trial.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Zentrum für Kinder- und Jugendmedizin, Bereiche Kinderkardiologie und Neuropädiatrie, Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/02/07**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **14 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Confirmed positive analysis for carrier status of Duchenne Muscular Dystrophy. Minimum age 14 years.

Exclusion criteria

Lack of confirmed positive analysis for carrier status of Duchenne Muscular Dystrophy.

Age under 14 years.

Any psychological or physical condition implying a contraindication to any of the



examinations included in the trial protocol.

Addresses

■ Primary Sponsor

**Universitätsklinikum Essen
Zentrum für Kinder- und Jugendmedizin
Klinik III, Bereiche Kinderkardiologie und Rheumatologie
Mr. Dr. med. Ulrich Neudorf**

Hufelandstrasse 55

45122 Essen

Germany

Telephone: **0201 723 3269**

Fax: **0201 723 5983**

E-mail: **ulrich.neudorf at uk-essen.de**

URL: [---]*

■ Contact for Scientific Queries

**Universitätsklinikum Essen
Zentrum für Kinder- und Jugendmedizin
Klinik III, Bereich Kinderkardiologie
Ms. Anne Schönecker**

Hufelandstrasse 55

45122 Essen

Germany

Telephone: **0201 723 84278**

Fax: **0201 723 5983**

E-mail: **anne.schoenecker at uk-essen.de**

URL: [---]*

■ Contact for Public Queries

**Universitätsklinikum Essen
Zentrum für Kinder- und Jugendmedizin
Klinik III, Bereich Kinderkardiologie
Ms. Anne Schönecker**

Hufelandstrasse 55

45122 Essen

Germany

Telephone: **0201 723 84278**

Fax: **0201 723 5983**

E-mail: **anne.schoenecker at uk-essen.de**

URL: [---]*

Sources of Monetary or Material Support



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

**Universitätsklinikum Essen
Zentrum für Kinder- und Jugendmedizin
Bereiche Kinderkardiologie und Rheumatologie
Mr. Dr. med. Ulrich Neudorf**

Hufelandstr.55

45122 Essen

Germany

Telephone: **0201 723 3269**

Fax: **0201 723 5983**

E-mail: **ulrich.neudorf at uk-essen.de**

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/11/14**

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.