Trial Description

Title

Hemodynamics during pacing-induced left bandle branch block compared to biventricular pacing

Trial Acronym

SILVER-BI

URL of the trial

[---]*

Brief Summary in Lay Language

**This study investigates whether a pacing-induced decrease of cardiac-output by right-ventricular pacing could be reversed by bi-ventricular pacing.
In order to measure the cardiac-output and to stimulate the heart at different sites, cardiac catheters are inserted in the inguinal vessels and advanced to the heart. All measurements last approximately 60 minutes.**

Brief Summary in Scientific Language

Hemodynamic changes under right-ventricular compared to bi-ventricular pacing in patients with chronic heart failure NYHA II-IV and narrow QRS complex

Organizational Data

- DRKS-ID: **DRKS00000667**
- Date of Registration in DRKS: **2011/01/25**
- 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.: **282/03 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1118-8323**

Health condition or Problem studied

- ICD10: **I50.9 - Heart failure, unspecified**
- ICD10: **I50.14 - [generalization I50.1: Left ventricular failure]**

Interventions/Observational Groups

- Arm 1: **right- and bi-ventricular pacing**

Characteristics

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

Primary Outcome

The increase of dP/dt during bi-ventricular stimulation is measured via an intracardiac pressure-wire. These measurements are performed during the procedure.

Secondary Outcome

Cardiac output is determined under different V-V-intervals. For these measurements an intracardiac pressure-wire is used.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/01/21**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Standard indication for an electrophysiology study (EPS)
• Heart failure NYHA II-IV despite optimal medical treatment
• Left ventricular ejection fraction less than or equal to 40%
• Narrow QRS-complex (less than 120ms)

Exclusion criteria

• Underage patients
• Pregnant women
• Patients who attend other studies at the same time
• Persistant or permanent atrial fibrillation

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Contact for Scientific Queries

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Sources of Monetary or Material Support

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

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Status

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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.*