

Trial Description

Title

Hemodynamic effects of multipolar left ventricular pacing

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Cardiac resynchronization therapy is standard for selected patients with heart failure. This study evaluates hemodynamic effects depending on the stimulation site.

Brief Summary in Scientific Language

Evaluation of hemodynamic effects of multipolar left ventricular pacing. We test the hypothesis that different stimulation modalities will have a differential impact on hemodynamics.

Organizational Data

- DRKS-ID: **DRKS00000573**
- Date of Registration in DRKS: **2010/10/12**
- 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.: **292/10 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50.1 - Left ventricular failure**

Interventions/Observational Groups

- Arm 1: **CRT patients, measurement of LV dP/dt in different pacing modes**

Characteristics

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

Primary Outcome

Identification of optimal pacing site according to invasive hemodynamic monitoring (LV dP/dt)

Secondary Outcome

Clinical outcome at 6 months

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

-

Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2010/10/07**
- 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

CRT indication according to guidelines, sinus rhythm, informed consent

Exclusion criteria

**no consent
permanent atrial fibrillation
implanted pacemaker or defibrillator
severe aortic stenosis
age < 18 years
pregnancy**

Addresses

■ Primary Sponsor

**Uniklinik Freiburg
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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/06/30**

Trial Publications, Results and other documents

DRKS-ID: **DRKS00000573**

Date of Registration in DRKS: **2010/10/12**

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- Paper **Vector selection of a quadripolar left ventricular pacing lead affects acute hemodynamic response to cardiac resynchronization therapy: a randomized cross-over trial.**

* *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.*