Trial Description

Title

Post-approval trial to evaluate the performance of the 10F-Reitan Catheter Pump in advanced heart failure patients

Trial Acronym

RCPerformance

URL of the trial

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Brief Summary in Lay Language

Evaluation of the 10F-RCP of heart failure patients with impaired kidney function.

Brief Summary in Scientific Language

Heart failure is a wide-spread condition and a severe disease with high mortality. According to American authorities there are 5.7 million Americans with heart failure. Once the diagnosis heart failure is established, 50% of patients will die within 5 years. The severity of the disease is also described by the NYHA class and in NYHA-class III (moderate symptoms) one year mortality is estimated at 10-15% and in NYHA-class IV (severe symptoms) at 30-40%. (Reisfield GM) Beside heart failure is life threatening it also costs economies a lot of money (e.g. $30.7 billion p.a. for the USA).
Most patients will therefore be on heavy medication. Despite the use of modern drugs many patients will experience a failing clinical condition with development of intractable heart failure. Because of the failing heart the organs will not be sufficiently supplied with blood and end-organ failure will occur. It is common to observe this as renal failure both because the function of the kidneys are pressure dependent, but also because some of the drugs used in the treatment of heart failure may exert a direct negative influence on the renal function. It is also common to observe a reduced liver function with increasing liver enzymes and attenuated production of coagulation factors. Some patients will experience episodes of acute decompensation with need of hospitalization and intensified medical treatment or even some kind of mechanical circulatory support.
The objective of this trial is to demonstrate that the 10F-RCP is safe and effective when used as short-term percutaneous circulatory support system in a real life end stage heart failure population with acute decompensation. The trial aims to confirm the hypothesis that the 10F-RCP improves organ perfusion (especially the kidneys) if compromised due to low perfusion pressure.

Organizational Data

- DRKS-ID: **DRKS00013205**
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Date of Registration in DRKS: **2019/04/01**

- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **7551 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

Health condition or Problem studied

- Free text: **acute decompensated heart failure (ADHF), cardiorenal syndrome (CRS)**
- ICD10: **I50.9 - Heart failure, unspecified**
- ICD10: **I42.0 - Dilated cardiomyopathy**
- ICD10: **I11 - Hypertensive heart disease**
- ICD10: **I25 - Chronic ischaemic heart disease**

Interventions/Observational Groups

- Arm 1: **Acute Decompensated Heart Failure (ADHF) patients with impaired kidney function will be treated für 24 hours with the 10F-Reitan Catherer Pump (10F-RCP). The 10F-RCP is percutaneous mechanical circulatory support (pMCS).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**

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- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Improvement in eGFR (based on MDRD formula) during 24 hours (Day 1) treatment with the 10F-RCP compared to baseline

Secondary Outcome

10F-RCP treatment induced changes in the following parameters: PCWP, CVP, PAP, MAP, CI, CO after a treatment duration of 24h compared to baseline data;

10F-RCP treatment induced changes in the following parameters: eGFR, SCr, Cystatin C, NT-proBNP during treatment (Day 1) and after treatment at Day 2, Day 3, Day 5 and Day 7 (or earlier if patient will be discharged or switched to another device therapy) compared to baseline data;

10F-RCP treatment induced changes in the following parameters: Lactate, AST/ALT, Troponine T, CKMB, CK, Myoglobine, LDH, Fibrinogene, and Urine Output during treatment (Day 1) and after treatment and additionally at Day 2 for Lactate and LDH.

INTERMACS level changes at baseline compared to 24 hours of treatment (Day 1), Day 2 and Day 7* (or earlier if patient will be discharged or switched to another device therapy);

Adverse Events (as risk-assessment): Major Bleeding; Hemolysis; Device Malfunction; Limb ischemia; Need for transfusion; thrombo-embolic complication; Neurologic complication.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Hochschule Hannover, Hannover**
- University Medical Center **Universitätsklinikum Heidelberg, Heidelberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/05/13**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

EF < 30%;
Cardiac index < 2.2 l/min/m2;
Informed consent;
Age between 18- 75 years old;
eGFR (MDRD) between 15 - 50 ml/min/1.73m²

Exclusion criteria

Renal Replacement Therapy (RRT);
Isolated Right Heart Failure, CVP ≥25 mmHg;
Cardiogenic shock due to acute coronary syndrome (ACS);
Restrictive Cardiomyopathy;
Hypertrophic Cardiomyopathy;
Heparin-Induced Thrombocytopenia (HIT);
Pulmonary vascular hypertension with PCWP < 15 mm Hg;
Systolic pressure less than 75 mm Hg for 30 mins;
Septic Shock;
Tortuous iliac arteries (Anatomical variations) OR Inability to gain access for introducer sheath or catheterization;
Severe Peripheral arterial disease (PAD);
Aortic diseases: Previous intravascular repair/stenting of aorta/femoral arteries, Aortic dissection chronic or acute, known aortic aneurysm, known severe calcified aorta-iliac disease or peripheral vascular disease;
Descending thoracic aortic diameter < 21 mm;
Aortic or mitral valve stenosis (II or greater);
Known coagulopathy ;

Significant blood dyscrasia, which is defined as any hematologic disorder characterized by intravascular hemolysis or associated with increased fragility of the red blood cell;
Lack of patient co-operation or no informed consent;
Pregnancy

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- 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.*