PROPER-LVAD

Preoperative Nutritional Optimization and Physical Exercise for Patients scheduled for elective Implantation of a Left-Ventricular Assist Device

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• Background

Heart failure, with a prevalence of 1 – 12% remains a major public health problem, especially in elderly and comorbid patients. The implantation of **ventricular assist devices (VAD)** represents an invasive treatment option for patients with end-stage heart failure, who are unresponsive to medical therapy. However, especially in comorbid patients, the potentially life-threatening complications occurring during the hospital stay, as well as the significant inflammation induced by the surgery, frequently induce the development of organ dysfunctions, which may negate any benefit from correction of the underlying disease. **Cardiac cachexia and sarcopenia** are highly prevalent in patients with heart failure and are known independent risk factors for worse postoperative outcome.

• Innovation

Patients scheduled for the implantation of a VAD are admitted to the hospital several weeks prior to surgery. This period opens the opportunity for the preoperative optimization of nutritional and functional status by a **combined of nutrition and exercise therapy before surgery, which is currently not part in clinical routine.**

• Objectives

We propose a pilot interventional trial of a combined preoperative **oral nutritional support (ONS) and physical exercise therapy** in adult patients scheduled for elective implantation of a VAD. The objective of this pilot study is to demonstrate **safety and feasibility** of a protocol that optimizes patients' nutritional and physical state to improve outcome following VAD implantation.

• Activities

This is a single-center interventional, assessor-blinded, clinical pilot trial. 20 patients will be randomized to standard care or to receiving oral nutrition support and in-bed cycling as demonstrated in Figure 1. Both interventions will start as soon as possible after randomization and continue until the day before surgery. Both interventions are standardized by operating protocols.

The patients will receive a dosage of **ONS adjusted to their weight**, nutritional risk, food intake and tolerance. The prescribed amount will be adjusted every 48 hours to ensure that the patient reaches the caloric and protein targets. The patients will **cycle in-bed** for 55 minutes per day at least 5 times per week. Standard safety criteria will be assessed prior to initiating cycling treatments. The in-bed cycling will be performed passively or actively with graded increasing resistance, while supervising the patient's vital parameters

Figure 1: Study flowchart

• Implementation

3CARE - cardiovascular critical care & anaesthesia evaluation and research" is an interdisciplinary research group at University Hospital RWTH Aachen. Intensivists, anaesthesiologists and cardiac surgeons combine their efforts to optimize the perioperative care of cardiac surgery patients.
The high-quality and international relevance of our work has been previously demonstrated by our publications and successful conduct of previous studies (e.g. the funded "Sustain CSX study", 2.9 M$ Canada and Germany, EIT Health "MACH VISIONS" funding 1.2 M€). Besides, our team has already successfully shown its expertise in planning and conducting large randomised controlled trials (RCT), especially in this unique patient population (SOS-LVAD trial). Our team comprises clinical and methodological expertise to address all relevant aspects regarding the conduct of clinical trails. Against this background, we don't expect any feasibility issues to occur.

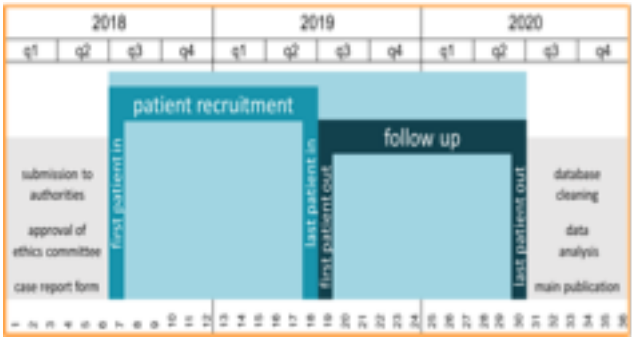

Figure 2: Study timeline

• Achievements

The study will start in August 2018 and will end in August 2020. The total study duration will be 36 months. The planned duration of study inclusion will be 12 months, including a follow-up period of 12 months as outlined in Figure 2.

• Resources

While preparing a draft for a third party funding for the definitive study, we are in contact with different nutrition companies to support this essential pilot study. An appreciable amount of money will be covered by own board funding. The following funding provided by Medical Nutrition International Industry would enable the conduct of the *PROPER LVAD Study*:

40 % Project manager 12 months, handling data management, preparation of benchmark reports	20.000 €
Other goods Server costs, database costs, IT support, statistical support	10.000 €
Total	30.000 €

Expected results

We expect the study demonstrate safety & feasibility to advance with a confirmatory clinical RCT for patients with end-stage heart failure.
We expect that this protocol will provide initial evidence about efficacy of the treatment by:

- Preventing the preoperative and overall loss of muscle mass and muscle function
- Promoting faster recovery faster after surgery through reduced rate of complications, infections and duration of hospital stay
- Improving physical and neuropsychological function, participation in life and quality of life

Expected impact

Even if malnutrition and frailty are recognized factors for a bad postoperative outcome, the **preoperative optimization** of nutritional sand physical state is **currently not part of the clinical routine.** If this protocol proves to be safe and feasible, a larger, adequately designed confirmatory clinical trial will follow in our established network, to determine the influence of the intervention on the clinical outcome of the patient. If the protocol proves to be beneficial, the combined intervention might be as well applicable **for all elective cardiac surgeries** and is transferable to **other major elective surgeries** involving an elevated risk for extended hospital stays or involving patients at high nutritional risk.
Thus, the proposed study might change clinical practice worldwide and benefit a large group of patients.

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Medical Nutrition International Industry