

Humedics starts LiMAx phase III trial on liver function analysis for severe liver surgery

First patients being included directly after study initiation in Berlin and Jena

Berlin, Germany, February 28, 2013 – Humedics GmbH, a specialist for real-time and mobile measurement of the individual liver function at the bedside of the patient, today announced the start of a clinical phase III trial. The main goal of this study is the early identification of low-risk patients after partial liver resection by the LiMAx test and improvements in patient management based on test results. After the initiation of first study centers in January, first patients already have been enrolled in Berlin and Jena.

The trial with the short title 'Fast-track LiveR' is a prospective, randomized, controlled, multi-centric, phase III study for the early identification of low-risk patients after partial liver resection with the LiMAx test. A major goal is to demonstrate the benefit for the patient and the impact on clinical thinking related to a different postoperative management (fast-track procedure) with immediate transfer of patients with good liver function from the recovery room to general ward.

Erwin de Buijzer, Managing Director of Humedics GmbH, commented the trial start: “The start of our phase III study is a milestone on the way to the approval of our LiMAx test and thus for the further company development of Humedics. We want to provide physicians with a new diagnostic procedure to enable a reliable liver function analysis prior and after liver surgery, to adapt therapy options respectively and thereby contributing to optimized and cost efficient healthcare. After we received the official approval for conducting the study from the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) and the positive vote of the ethics committee end of 2012 we were able to start immediately with the initiation of the first study centers early this year. We are very excited that Berlin and Jena already have enrolled the first patients within such a short time span.”

Chief Investigator PD Dr. Martin Stockmann from Charité – Universitätsmedizin Berlin at the Campus Virchow Hospital, Dept. of General, Visceral and Graft Surgery, added “Liver surgery with a partial removal of the liver implies a general risk of postoperative complications including severe complications like liver failure. So far, an analysis of the remaining liver function was not possible. The LiMAx test of Humedics has the potential to address this medical need and thus to optimize and individualize patient management. In the clinical practice this may result, for example, in decision-making on the basis of liver function analysis if a patient needs to be further treated in an Intensive Care Unit or if he can be transferred to general ward.”

Prof. Dr. Utz Settmacher, Director of the Dept. of General and Visceral Surgery and responsible for the Fast-track LiveR study center at the Jena University Hospital, said: “With the LiMAx test we are able to directly determine the liver function and thus to assess much better the outcome of liver surgery. This is new and both – clinician and patient – benefit from the test. We are very pleased to take part in this important trial and also about the fact that we have been able to include patients within the first days after study initiation.”

Fast-track LiveR Trial

Fast-track LiveR is a prospective, randomized, controlled, multi-centric, phase III study for the early identification of low-risk patients after partial liver resection with the LiMAx test. The LiMAx test determines the actual liver function in real-time. The test includes the application of the diagnostic investigational medicinal product, ¹³C-Methacetin solution for infusion and a breath test involving the use of Humedics' FLIP device for measurement and analysis. 120 patients with different types of liver tumors and designated for open liver surgery are to be included in the study. Two study arms have been set up; each planned to enroll 60 patients. The LiMAx group is subject to a perioperative patient management according to the fast-track procedure. This includes a pre- and postsurgical analysis of the liver function with the LiMAx test. In the control group the perioperative patient management is performed according to current clinical standards. The trial will be conducted at different study centers in Germany and is expected to be completed by the end of 2013.

LiMAx Test

The underlying principle of the LiMAx test involves the following steps: At first, a ¹³C-Methacetin solution is administered intravenously. ¹³C-Methacetin is metabolized in the liver to paracetamol and ¹³CO₂ and the latter is exhaled in the breath. The exhaled air is collected via a respiratory mask. Subsequent measurement of ¹³CO₂ using laser detection in the FLIP device provides a quantitative determination of the liver capacity and thus the liver function.

About Humedics

Humedics has developed a breath test (LiMAx test) based diagnostic system including the medical device FLIP. More than 100 million people world-wide suffer from chronic liver diseases (i.e. cirrhosis, hepatitis, fatty liver, metabolic disorders and tumors). The LiMAx test enables the clinician to quantitatively determine the individual liver function capacity for a patient within minutes. This allows for selecting treatment strategies optimally adapted to the individual patients liver status. Current applications include diagnosis of the liver function before and after liver transplantation, liver surgery planning (e.g. assessment of the amount of liver to be removed without potentially increasing the risk for liver failure) and assessment of diseases such as liver cirrhosis. Up to date the LiMAx test has been used more than 8,500 times and the results have been published in highly respected scientific journals.

Humedics is equity financed by Peppermint VenturePartners (managing the Charité Biomedical Fund) as lead investor together with VC Fonds Technologie managed by IBB-Beteiligungsgesellschaft, ERP Startfonds of the KfW, Ventegis and High-Tech Gründerfonds. The funds enable Humedics to complete the final development and early commercialization of its proprietary and CE-marked diagnostic system to determine the liver function of patients in real time.

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