MICROB-PREDICT

ALB-TRIAL. A clinical trial of human albumin in the treatment of decompensated cirrhosis guided by the MICROB-PREDICT biomarker

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.

OUR VISION

MORE EFFECTIVE, MORE INDIVIDUALISED AND MORE TARGETED TREATMENTS

MICROB-PREDICT aims to develop personalized treatment based on human microbiome (microbes in the body) to prevent and treat complications of cirrhosis, such as ascites, acute variceal bleeding, infections requiring hospitalization or hepatic encephalopathy and failure of other organs and to reduce the risk of dying due to complications of cirrhosis.

OBJECTIVES OF THE ALB-TRIAL

The aim of the ALB-TRIAL within the MICROB-PREDICT project is to validate a microbiome-derived biological marker to predict how well the body responds to treatment with albumin in patients with cirrhosis. The biological marker has been developed within the MICROB-PREDICT project and will be tested in a European randomized, double-blinded, placebo-controlled trial with patients enrolled from eight European centres. The aim is to provide a clinical tool for personalized treatment with albumin that can identify patients who are likely to clinically benefit from the long-term treatment with human albumin (reduced or improved symptoms and lower risk of death).

FOR WHOM?

Adult persons with decompensated liver cirrhosis.

WHAT TREATMENT?

Infusion of albumin or placebo through the vein every 10th day ± 3 days for 6 months at the hospital in day-care setting.

WHAT IS ASSESSED?

The number of complications of cirrhosis, such as variceal bleeding, ascites, infection requiring hospitalization, acute kidney injury and hepatic encephalopathy in 6 months of follow-up. In addition, quality of life, hospital admissions, number of treatment-related adverse events and a health economic evaluation will be assessed in the ALB-TRIAL.

DOES THE PROJECT COMPLY WITH THE ETHICAL AND LEGAL STANDARDS?

A dedicated team within MICROB-PREDICT ensures that the project complies with the ethical and legal standards. **You can read more at:** D8.7 Checklist for participants to assure informed consent/other mechanisms for those unable to give a written consent.

Link to D8.7 checklist for participants on **MICROB-PREDICT website**

WHY IS PERSONALIZED TREATMENT WITH ALBUMIN STUDIED?

End-stage cirrhosis causes symptoms, loss of quality of life, increases the risk of dying, and has a large socioeconomic impact because of high health care costs and the persons' inability to work or seek employment. Therefore, it is crucial to develop novel treatments and help persons with cirrhosis earlier, faster and better.

Albumin is the most abundant protein in the human blood circulation. Albumin has several important functions, such as the reduction of inflammation, which is presumed to be beneficial in patients with end-stage cirrhosis, especially as long-term administration. However, not all patients appear to benefit equally from albumin in previous clinical studies. Therefore, it is important to identify patients who are likely to benefit from albumin therapy, using a biological marker which has been identified within the MICROB-PREDICT project, in order to provide personalized treatment with albumin in the future.

Patients benefits:

- reduced or improved symptoms
- better quality of life
- lower risk of death
- personalized therapy based on predicted treatment effect

MEMBERS

MICROB-PREDICT is an international research project that brings together 22 institutions from 10 European countries.

Scientific coordination

EF Clif
EUROPEAN FOUNDATION FOR THE STUDY OF CHRONIC LIVER FAILURE

Principal investigator

OUH
Odense University Hospital
Svendborg Hospital

ALB-TRIAL: BASIC FACTS AND FIGURES

ALB-TRIAL: FULL PROJECT TITLE	A randomized multicentre, double-blinded and placebo-controlled, trial of human albumin in the treatment of decompensated cirrhosis guided by the MICROB-PREDICT biomarker
EMBEDDED IN	**MICROB-PREDICT:** **MICROB**iome-based biomarkers to **PREDICT** decompensation of liver cirrhosis and treatment response
START DATE	01 January 2019
DURATION TIME	75 months (6 ¼ years)
PARTICIPANTS	8 centres in 7 countries
EC FUNDING	15 million €
PROJECT WEBSITE	microb-predict.eu/for-patients-public/english/clinical-trial

Contact

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