MICROB-PREDICT

MICROBiome-based biomarkers to PREDICT decompensation of liver cirrhosis and treatment response

D9.6 Brochure to inform in brief about MICROB-PREDICT for participants involved in the clinical study

Project acronym:	MICROB-PREDICT
Grant Agreement:	825694
Project Duration:	01 January 2019 – 31 March 2025 (75 months)
Version:	V1
Date:	29/09/2021
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1. Executive Summary

MICROB-PREDICT strives to increase awareness of patients and the general public of the role of the microbiome in cirrhosis and related complications. A project brochure has been developed to inform in brief candidate participants and their relatives about the MICROB-PREDICT project and the ALB-TRIAL, a randomised clinical trial in patients, stratified by the treatment response to albumin.

2. Deliverable report

The brochure has been developed in close collaboration with the clinical trial investigators, the bioethics and legal partner and is available in English language. Translation in Danish, Hungarian, Flemish, Dutch, Spanish and German is anticipated prior to the start of the clinical trial. The brochure can be used for both printing and web-use.

3. Tables and other supporting documents where applicable and necessary

Please see attachments 1 and 2 attached to this report.

4. Acknowledgement and Disclaimer

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

This report reflects only the author's view and the Commission is not responsible for any use that may be made of the information it contains.


MICROB-PREDICT
Alb-trial. A clinical trial of human albumin in the treatment of decompensated cirrhosis guided by the Microb-Predict biomarker
Principal investigator: Professor Aleksander Krag, Odense University Hospital, Denmark
Deputy Principal investigator: Professor Jonel Trebicka, European Foundation for the study of chronic liver failure, Barcelona, Spain
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825694.
IS PERSONALIZED
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UMIN STUDIED?
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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 admi-
nistration. 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
checklist for participants to
assure informed consent/other
mechanisms for those unable to
give a written consent

OUR VISION

MICROB-PREDICT aims to develop personalised treatment based on human microbiome (microbes in the body) to prevent and treat complications of cirrhosis, such as ascites, acute variceal bleeding,

MORE EFFECTIVE, MORE INDIVIDUALISED AND MORE TARGETED TREATMENTS

infections requiring hospitalization or hepatic encephalopathy and failure of other organs and reduce the risk of dying due to complications of cirrhosis.

OUR VISION

MORE EFFECTIVE, MORE INDIVIDUALISED AND MORE TARGETED TREATMENTS

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 removes toxic substances from the blood. The biological marker has been developed within the MICROB-PREDICT project and will be tested in a European randomised, double-blinded, placebo-controlled trial with patients with cirrhosis. The Microb-Predict marker has been developed in a European randomised, double-blinded, placebo-controlled trial with patients with cirrhosis. The trial is to provide a clinical tool for personalised 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 x 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 hospitalisation, acute kidney injury and hepatic encephalopathy in 6 months, quality of life, hospital admission, 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:
D8.2 Checklist for participants to assure informed consent and that investigators for those unable to give a written consent

ALB-TRIAL: BASIC FACTS AND FIGURES

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

Contact

PRINCIPAL INVESTIGATOR	**Professor and Head of Hepatology Aleksander Krag** Odense Universitetshospital (OUH)
MICROB-PREDICT COORDINATOR	**Professor Jonel Trebicka** European Foundation for the study of chronic liver failure, Barcelona, Spain
PROJECT MANAGEMENT	**concentris research management gmbh** pmo@microb-predict.eu

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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 and stage cirrhosis. Moreover, albumin is effective in reduction of bacterial infections and kidney failure, 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 personalised 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

MICROB-PREDICT

Alb-trial. A clinical trial of human albumin in the treatment of decompensated cirrhosis guided by the Microb-Predict biomarker

Principal Investigator: Professor Aleksander Krag, Odense University Hospital, Denmark.

Deputy Principal investigator: Professor Jonel Trebicka, European Foundation for the study of chronic liver failure, Barcelona, Spain

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

ALB-TRIAL: BASIC FACTS AND FIGURES

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PROJECT MANAGEMENT	**concentris research management gmbh** pmo@microb-predict.eu

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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,

of dying due to

MEMBERS

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



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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Deputy Principal investigator:
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European Foundation for the Study of Chronic Liver Failure,
Barcelona, Spain

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OUR VISION



MORE EFFECTIVE, MORE INDIVIDUALISED AND MORE TARGETED TREATMENTS

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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**

Photo credits: Stanhei @ Adobe Stock

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Patients benefits:

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

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MEMBERS

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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

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