LIVERHOPE

Simvastatin and Rifaximin as new therapy for patients with decompensated cirrhosis

LIVER CIRRHOSIS DISEASE BURDEN AND MEDICAL NEED

Liver cirrhosis, similarly to congestive heart failure, chronic obstructive pulmonary disease or chronic kidney disease, represents the end-stage of a chronic disorder which results in severe and permanent damage of a vital organ. The most common cause of death of patients with cirrhosis is the so-called acute-on-chronic liver failure (ACLF), a syndrome characterized by development of failure of multiple organs.

In recent years, liver cirrhosis has emerged as a major cause of global health burden, and one of the leading causes of death in adults worldwide. In adults within the 45-65 age range, cirrhosis was the 10th cause of death in males and the 15th cause of death in females. The number of deaths due to cirrhosis in Europe has been estimated to be around 170,000 annually, with varying mortality rates in different European countries.

Moreover, liver cirrhosis is one of the leading diseases in disability-adjusted life years (DALYs) and has a major effect in patients' quality of life, indicating that cirrhosis is one of the chronic diseases with greatest impact in patients' life.

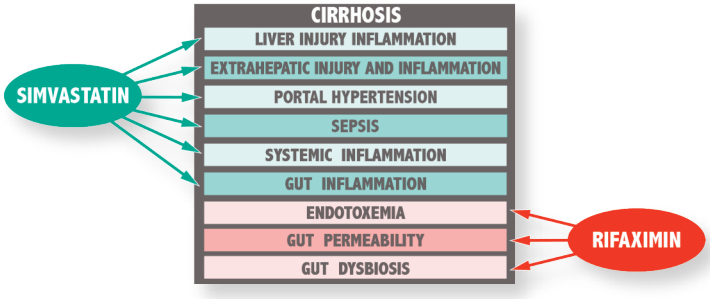
Treatment of cirrhosis is currently based on symptomatic management of complications and has not changed substantially in the last 20 years.

There is an unmet medical need for new therapies that target the pathobiology of cirrhosis in order to improve the patients' quality-of-life and to increase the survival of patients.

LIVERHOPE FOCUS

The objective of the LIVERHOPE project is to evaluate a novel therapeutic strategy for patients with cirrhosis based on a combination of rifaximin and simvastatin, targeting the main pathophysiological mechanisms of disease progression:

- The impairment in the gut liver-axis will be targeted with rifaximin, a non-systemic antibiotic that decreases the gut permeability, reducing systemic endotoxin levels characteristics of cirrhosis, modulating the intestinal microbiome.
- The inflammatory reaction will be targeted with simvastatin, a drug of the statin family that decreases systemic and hepatic inflammation, improves the altered hepatic microcirculation, decreases portal hypertension, and reduces fibrosis progression.

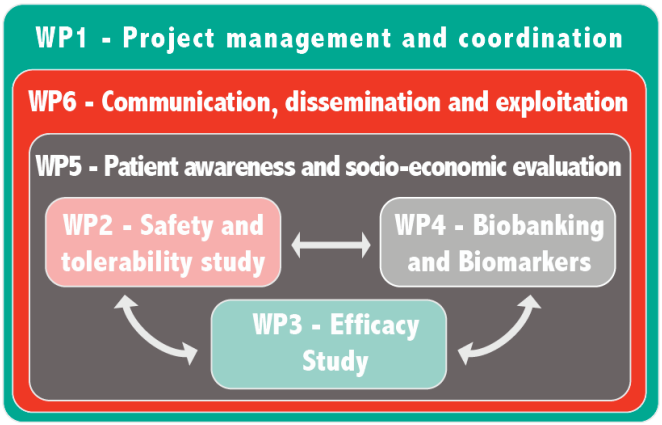


The specific objectives of LIVERHOPE are:

- To perform two randomized double-blind trials to investigate the safety, tolerability and efficacy of the combination of simvastatin plus rifaximin in patients with decompensated cirrhosis to halt progression to ACLF, decrease complications of the disease, reduce hospital readmissions, improve patients quality-of-life, and increase survival
- To identify biomarkers of response to treatment and disease progression that can be useful in clinical practice
- To disseminate adequately the results of the study so that the information reaches the patient population who can benefit from this new therapeutic strategy
- To increase awareness about chronic liver diseases in European countries so that preventive measures can be established to decrease the burden of disease
- To reduce social stigmatization of patients with chronic liver diseases

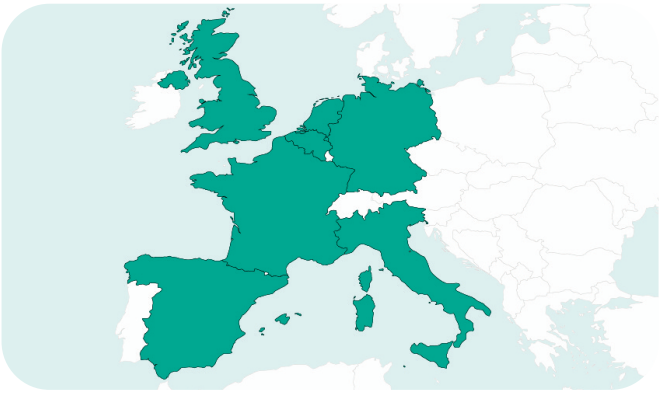
LIVERHOPE DESIGN

The specific objectives of LIVERHOPE will be achieved in six work packages (WP).



LIVERHOPE ALLIANCE

The LIVERHOPE consortium is coordinated by the Consorci Institut D'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Catalonia, Spain and brings together 16 partners from 7 different European countries with industrial and academic background.



The academic partners contribute by their well-recognized expertise in pathology, patient care, mono-/multicentre trials, advanced biomarker programs, collaboration with health insurances, and translational orientated infrastructure. The industrial partners contribute to the project success with their documented expertise in pharmaceutical and clinical research, drug discovery, pre-clinical and clinical development, systems biology solutions.

Participants

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LIVERHOPE

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