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.

**LIVERHOPE DESIGN**

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

- **WP1 - Project management and coordination**
- **WP2 - Safety and tolerability study**
- **WP3 - Efficacy Study**
- **WP4 - Biobanking and Biomarkers**
- **WP5 - Patient awareness and socio-economic evaluation**
- **WP6 - Communication, dissemination and exploitation**

**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.
Simvastatin and Rifaximin as new therapy for patients with decompensated cirrhosis

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