Personalised human albumin in patients with cirrhosis and ascites: design and rationale for the ALB-TRIAL - a randomised clinical biomarker validation trial

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Abstract

Introduction: Human albumin is used in the treatment of complications of cirrhosis. However, the use of long-term human albumin administration is costly and resource demanding for both patients and healthcare systems. A precision medicine approach with biomarkers to predict human albumin treatment response, so-called predictive biomarkers, could make this a viable treatment option in patients with cirrhosis and ascites.

Methods and analysis: ALB-TRIAL is a multinational, double-blind, placebo-controlled randomised controlled trial. We aim to validate a predictive biomarker, consisting of a panel of circulating metabolites, to predict the treatment response to human albumin in patients with cirrhosis and ascites. All enrolled patients are stratified into a high-expected or low-expected effect stratum of human albumin based on the biomarker outcome. After stratification, patients in each group are randomised into either active treatment (20% human albumin) or corresponding placebo (0.9% NaCl) every 10th day for 6 months. The primary outcome is the cumulative number of liver-related events (composite of decompensation episodes, transjugular intrahepatic shunt insertion, liver transplantation and death). Key secondary outcomes include time-to-event analysis of primary outcome components, an analysis of the total healthcare burden and a health economic analysis.

Ethics and dissemination: The trial obtained ethical and regulatory approval in Denmark, Germany, the Netherlands, Belgium, Hungary and Spain through the Clinical Trials Information System (CTIS) from 13 February 2023, while UK approvals from the Health Regulatory Authority, Medicines and Healthcare products Regulatory Agency and Research Ethics Committee are pending. Findings will be published in peer-reviewed journals, presented at conferences, communicated to relevant stakeholders and in the public registry of CTIS, following trial completion.

Trial registration number: NCT05056220 EU CT: 2022-501006-34-01.