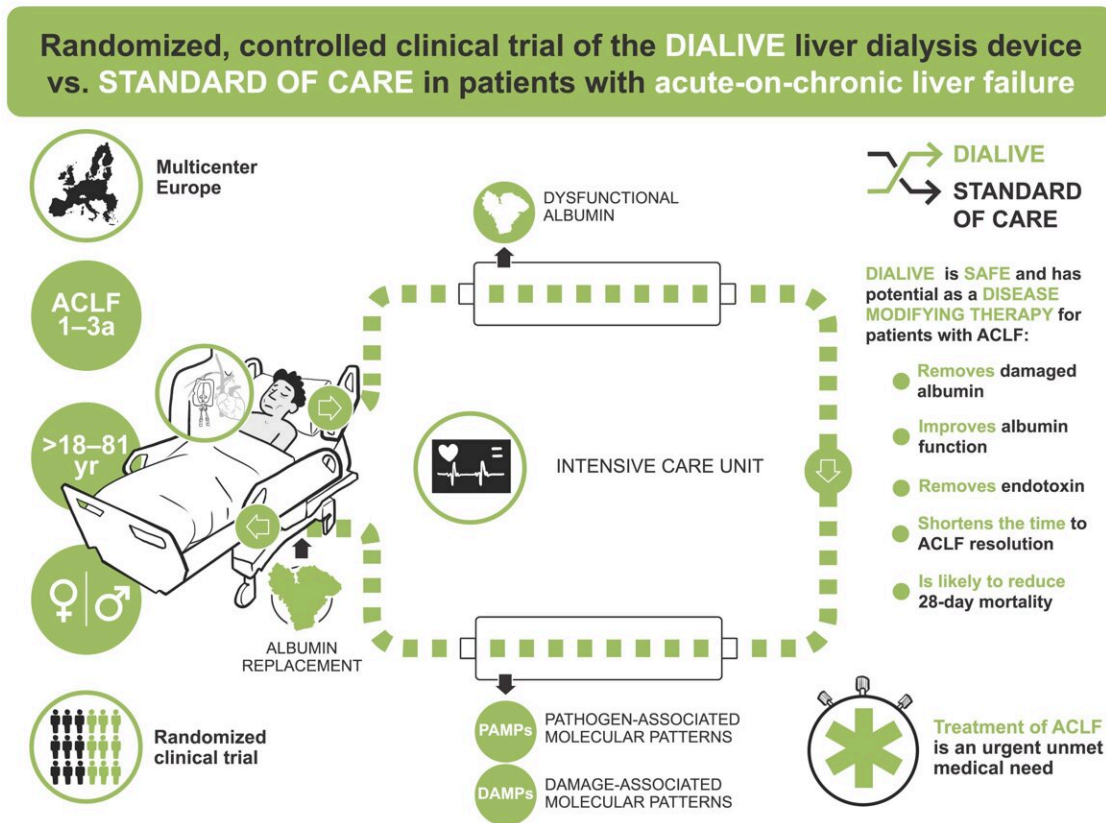


Clinical trial finds liver dialysis device is safe and effective for treating severe liver failure

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Randomized, controlled clinical trial of the DIALIVE liver dialysis device vs. standard of care in patients with acute-on-chronic liver failure (ACLF). Credit: *Journal of Hepatology*

The first successful in-patient trial of liver dialysis has been completed

by researchers from UCL, the Royal Free Hospital, UCL spin-out Yaqrit and their collaborators.

The DIALIVE device, invented by researchers at UCL's Institute for Liver and Digestive Health, was found to be safe and was associated with substantial improvement in the severity of symptoms and [organ function](#) in a greater proportion of patients with acute-on-chronic liver failure (ACLF), when compared with patients receiving standard of care.

The next step will be a larger clinical trial, which if successful could see DIALIVE approved for [clinical use](#) within the next three years.

Worldwide, it is estimated that there are around 100 million people living with cirrhosis of the liver and 10 million who have cirrhosis plus an additional complication. Around three million of those individuals have ACLF, a condition that can cause [liver function](#) to suddenly decline, placing individuals at high risk of short-term death.

The UK sees around 15,000 ACLF patients each year whose [treatment costs](#) the NHS in the region of £100,000 per patient, without improving their mortality risk.

The liver is a complex organ that performs over 500 functions, including removal of harmful substances from the blood and absorbing nutrients. One of its roles is to produce large quantities of a protein called albumin, which travels around the body acting as a sort of 'mobile liver' that absorbs unwanted substances.

But when liver function is seriously reduced, such as through alcohol abuse, obesity or viral infection, less albumin is produced. In ACLF, its function is also seriously impaired; [liver cells](#) die and the gut begins to leak bacteria into the bloodstream, which can cause an inappropriate immune response and multiorgan failure. DIALIVE was designed to

address these mechanisms that drive mortality of ACLF patients.

This study is the first-in-human randomized, controlled clinical trial of a liver dialysis device. It was performed with the aim of assessing the safety of DIALIVE to treat ACLF patients and to observe its clinical effects. A total of 32 patients were treated with DIALIVE or standard of care for up to five days and the outcomes were recorded at days 10 and 28.

The results showed that DIALIVE treatment was associated with significantly faster reversal of ACLF compared with standard of care, with ACLF resolving in about twice the number of patients. This clinical improvement was associated with significant impact on the mechanisms underlying the development of ACLF.

DIALIVE treatment led to a significant reduction in endotoxins, which are released when bacteria die, and improved albumin function. Biomarkers of systemic inflammation, such as cytokines, endothelial function and markers of cell death, all improved. Despite receiving as little as three days' treatment, patients whose ACLF resolved remained in remission for 28 days afterwards.

Dr. Banwari Agarwal, Chief Investigator of the DIALIVE trial from the Royal Free Hospital and Honorary Associate Professor at the UCL Division of Medicine, said, "It gives me enormous pleasure to see the promise of this novel liver dialysis device for the treatment of acute-on-chronic liver failure."

"The intervention has the potential to transform the care provided to the ever-increasing number of patients and their families suffering from the effects of living with what is essentially a terminal illness for many. It has the potential to transform the therapeutic options available to clinicians across the world for patients with ACLF."

The next step will be to conduct a larger trial with more patients to confirm DIALIVE's safety and effectiveness. One of the additional metrics to be assessed will be the impact on patient mortality of DIALIVE versus other available care.

Professor Rajiv Jalan (UCL Institute for Liver and Digestive Health, part of the UCL Division of Medicine), inventor of DIALIVE and co-founder of Yaqrit, said, "As academics it can be difficult to define a disease then translate this knowledge into a clinical solution that makes a real difference to people's lives. So the results of the DIALIVE trial are an emotional moment, which wouldn't have been possible without scientific collaboration between the UK, European colleagues and funding from the European Commission. My hope is that within a few years we will start to fulfill the urgent unmet need for treating acute-on-chronic liver failure and improve outcomes for patients."

Carrie Morgan, Senior Vice President of Clinical Operations at Yaqrit, said, "We are at an exciting stage of the development of DIALIVE and the results of this trial are extremely encouraging. Our unwavering focus remains on putting the individual at the center of our efforts, working tirelessly towards a brighter future for all those impacted by chronic liver disease."

The trial is the latest step on a long journey for UCL and Royal Free Hospital researchers, that began with the identification of acute-on-chronic liver failure as a distinct clinical entity in 2001. This work led to DIALIVE, which was invented by Professors Rajiv Jalan and Nathan Davies, based in the Liver Failure Group at UCL's Institute for Liver and Digestive Health, part of UCL Division of Medicine.

The research is published in the *Journal of Hepatology*, and the [intellectual property](#) behind the technology was patented by UCL in 2009 and licensed to a spin-out company, Yaqrit.

Dialysis is a technique to clean the blood of harmful substances, more familiar in the treatment of those with reduced or no kidney function. Kidney dialysis patients must undergo treatment for several hours each day in order to live. Due to the liver's regenerative qualities, however, it is expected that [liver](#) dialysis will be able to provide longer term benefits after a short stint of treatment lasting several days.

More information: Banwari Agarwal, Randomized, Controlled Clinical Trial of the DIALIVE Liver Dialysis Device versus Standard of Care in patients with Acute on Chronic Liver Failure', *Journal of Hepatology* (2023). [DOI: 10.1016/j.jhep.2023.03.013](https://doi.org/10.1016/j.jhep.2023.03.013)

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