



Media release

Hope for Cirrhosis Patients: Researchers release results at EASL 2023 Congress demonstrating that a Faecal Microbiota Transplant can restore gut health and improve patient outcomes.

A pioneering study led by Professor Debbie L Shawcross at King's College London based on a placebo-controlled randomised single-blinded feasibility trial of 32 patients with advanced cirrhosis involving a faecal microbiota transplant (FMT).

Thursday June 22, 2023 (Vienna, Austria) – Researchers today confirmed that they have been able to demonstrate that Faecal microbiota transplant can treat advanced cirrhosis by restoring a person's gut barrier function and augmenting the metabolism of the deadly toxin ammonia. The important results of the feasibility trial were presented by co-lead **Dr Lindsey Ann Edwards**, FMT Research Director at King's College London at the Official Scientific Press Conference on the second day of the [EASL Congress 2023](#) taking place this week at the Messe Wien Exhibition Congress Centre in Vienna.

Some 8,000 scientists, doctors, public health officials, industry representatives and affected communities are attending the event which runs through until Saturday June 24. The congress is convened annually by the [European Association for the Study of the Liver \(EASL\)](#).

Patients suffering from cirrhosis experience reduced gut bacterial diversity with an overabundance of pathobionts (harmful microbes) in their gut microbiome. This imbalance, combined with compromised gut barrier function, allows bacteria to translocate (pass into) the body and a reduced antimicrobial immune response, heightens the risk of infection and mortality.

The placebo-controlled randomised single-blinded feasibility trial of 32 patients with advanced cirrhosis involving a faecal microbiota transplant (FMT) led to engraftment and restoration of gut diversity and reduced ammonia retention in the blood. The landmark trial demonstrated for the first time that FMT modifies the gut microbiota, enhancing intestinal barrier function, antimicrobial mucosal immunity, and ammonia metabolism.

"This exciting study confirms the growing awareness in recent times of the link between gut health and liver disease and suggests that modulating the microbiome and restoring crucial functions holds tremendous potential for improving patient outcomes and will be key to our scientific understanding around liver health for years to come," said **Thomas Berg**, EASL Secretary-General and Head of the Division of Hepatology at Leipzig University Medical Center in Germany, who was not involved in the research.

"These initial findings are promising news for patients with chronic liver disease who are in desperate need of alternative treatment options," said Chief Investigator **Debbie L**

Shawcross, Professor of Hepatology and Chronic Liver Failure at King's College London, who is standing for position of EASL Vice-Secretary this week.

In the trial, the faecal transplant was raw material administered via an endoscopy. As a next step the researchers have since manufactured faecal capsules that patients can ingest in a similar way to their other medication.

Professor Shawcross and the team at King's College London have commenced the PROMISE trial a 300-patient multicentred placebo-controlled randomised controlled trial of the FMT capsules that will involve multiple dosing of the capsules and follow-up for 2 years. Alongside, this they are working with the British Liver Trust UK, The Policy Institute King's College London and other key stakeholders including EASL to integrate this treatment into clinical guidelines.

"Patients with chronic liver disease are often prescribed antibiotics, however, they are at high risk of multidrug-resistant infections and this is contributing to the global health crisis of antimicrobial resistance," said Dr Lindsey Ann Edwards, Scientific lead on the feasibility trial.

"There is an urgent and unmet need to tackle infection and antimicrobial resistance in chronic liver disease. Reducing the susceptibility and incidence of infection in this specific group of individuals will lead to fewer prescriptions of antibiotics, reduced hospitalisations and reduced incidence of antimicrobial resistance, which could be of huge global societal benefit."

Other announcements made at today's press conference included the results from the first-ever trial of opioid substitute drug Naltrexone in people with cirrhosis showing a reduction in alcohol dependence; an AI model that accurately predicts the survival rates of cirrhotic patients treated by the combination drugs atezolizumab and bevacizumab; promising results from a Phase III study showcasing the potential of Resmetirom in treating patients with Nonalcoholic steatohepatitis (NASH) and liver fibrosis and the end results of an eight year-old study on the long-term effectiveness of Tenofovir Alafenamide in the management of chronic hepatitis B.

Today's official press conference highlighted five studies, selected from over 1,800 abstracts being presented at EASL Congress 2023 this week.

Gut Restoration: FMT offers new hope for cirrhosis patients

Faecal Microbiota Transplant (FMT) emerges as a promising therapy that can bring back diversity to the gut and enhance liver function in cirrhosis patients, particularly improving hepatic encephalopathy.

Lindsey A Edwards of King's College London, United Kingdom, presented the trial's remarkable results, demonstrating that FMT effectively modifies the gut microbiota, leading to strengthened intestinal barrier function, fortified mucosal immunity, and improved ammonia metabolism. These significant findings bring a renewed sense of hope for patients grappling with advanced cirrhosis, offering a potential breakthrough in their treatment and survival.

Abstract: Faecal microbiota transplant restores gut barrier function and augments ammonia metabolism in patients with advanced cirrhosis: a randomised single-blind placebo-controlled trial (GS- 007)

Session: General Session II Friday June 23, 10:30 – 10:45 CEST

Breaking the chains of alcohol addiction: Naltrexone's safe and effective path to abstinence in cirrhotic patients

Addressing the critical need for effective treatments in alcohol-associated liver diseases, a double-blind randomised trial explored the safety and efficacy of naltrexone in cirrhotic patients with alcohol use disorder (AUD).

Manasa Alla, of the Institute of Liver and Biliary Science, New Delhi, India, reported that naltrexone can be safely administered to patients with compensated cirrhosis, effectively achieving abstinence and reducing alcohol craving scores at the 3-month mark. With continued alcohol use being a major determinant of long-term outcomes in alcohol-related liver diseases, these findings highlight the potential of naltrexone to positively impact patient survival and well-being.

Abstract: Naltrexone is safe and effective in achieving abstinence and reducing alcohol craving in cirrhotic patients. a double-blind randomised placebo-controlled trial (GS – 008 – YI)

Session: General Session II, Friday June 23 10:45 – 11:00 CEST **Unlocking new horizons in NASH and liver fibrosis treatment: MAESTRO-NASH reveals promising results**

The primary endpoint results of the MAESTRO-NASH study were unveiled, offering promising insights into the treatment of patients with NASH and liver fibrosis. MAESTRO-NASH (NCT03900429) is an ongoing 54-month Phase 3 clinical trial evaluating the effect of Resmetirom, administered once daily at doses of 80 mg or 100 mg, compared to placebo in NASH patients with liver fibrosis.

Stephen Harrison, of Pinnacle Clinical Research, San Antonio, United States, reported the analysis of Week 52 primary endpoints, which demonstrated that both Resmetirom doses achieved NASH resolution and fibrosis reduction on liver biopsy, indicating substantial efficacy. Resmetirom treatment was generally well-tolerated, exhibiting a favourable safety profile. These results highlight the potential of Resmetirom to offer significant benefits to patients with NASH and liver fibrosis.

Abstract: Primary results from MAESTRO-NASH a pivotal phase 3 52-week serial liver biopsy study in 966 patients with NASH and fibrosis (GS-001)

Session: General Session I, Thursday June 22, 10:30 – 10:45 CEST

AI predicts response to Atezolizumab-Bevacizumab in advanced liver cancer

The standard-of-care therapy for advanced hepatocellular carcinoma (HCC) involves atezolizumab-bevacizumab combination treatment. However, only a minority of patients show objective responses, necessitating the development of predictive biomarkers to enhance patient stratification and outcomes.

Julien Calderaro, of the Henri Mondor University Hospital, Créteil, France, presented an innovative study, whereby researchers developed a deep-learning model that accurately estimated the ABRS gene expression value directly from HCC histological digital slides. This model successfully predicted progression-free survival in treated patients, demonstrating the potential for cost-effective and rapid implementation of AI-based biomarkers in clinical practice. Furthermore, the combination of AI prediction heat maps with spatial transcriptomics provided valuable insights into the molecular features associated with areas of high predictive value, paving the way for further advancements in personalised medicine.

Abstract: Deep learning predicts sensitivity to atezolizumab-bevacizumab from digital slides of hepatocellular carcinoma (LBO – 04)

Session: Late Breaker, Saturday June 24, 11:45 – 12:00 CEST

Sustained success: Tenofovir Alafenamide demonstrates long-term efficacy in chronic Hepatitis B

The final results of two Phase 3 studies assessing the long-term efficacy of tenofovir alafenamide (TAF) in HBeAg-positive and -negative chronic hepatitis B patients were presented.

Maria Buti, of Hospital Universitario Vall d’Hebron, Barcelona, Spain, reported that over an impressive treatment duration of up to 8 years, TAF demonstrated noninferior efficacy compared to tenofovir disoproxil fumarate (TDF) in the double-blind assessments. Virologic suppression rates remained consistently high across all groups, with up to 33% achieving HBeAg/HBeAb seroconversion. While HBsAg loss was modest ($\leq 5\%$), these long-term findings underline the sustained effectiveness of TAF in managing chronic hepatitis B.

Abstract: Long-Term Efficacy of Tenofovir Alafenamide in Chronic Hepatitis B Patients treated for up to 8 years in 2 phase 3 studies (OS-067)

Session: Abstract Session – Viral hepatitis B/D – Current treatments - Friday June 23, 9:00 – 9:15 CEST

Further Information

Media Registration: Accredited media can apply for free registration [here](#)

Programme: For updates to the congress programme see [here](#)

Press Programme: All EASL Congress 2023 Official Press Conferences held onsite will also be broadcast live on Zoom for registered media.

Embargo Policy: Media representatives are asked to familiarise themselves with the official policy EASL Congress 2023 [Embargo Policy](#)

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About [EASL Congress 2023](#)

EASL Congress (previously known as the International Liver Congress) is EASL’s flagship event, attracting scientific and medical experts from around the world to learn about the latest in liver research and exchange clinical experience. Attending specialists present, share, debate and conclude on the latest science and research in hepatology, working to enhance the treatment and management of liver disease in clinical practice.

About The [European Association for the Study of the Liver \(EASL\)](#)

Since its foundation in 1966, this not-for-profit organisation has grown to over 5,200 members from all over the world, including many of the leading hepatologists in Europe and beyond. EASL is the leading liver association in Europe, having evolved into a major European association with international influence, and with an impressive track record in promoting research in liver disease, supporting wider education, and promoting changes in European liver policy.