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**Rice-derived recombinant human serum albumin as an alternative to human plasma for patients with decompensated liver cirrhosis: a randomised, double-blind, positive-controlled and non-inferiority trial**

Niu J, Gao Y, Wang G*, et al.* Rice-derived recombinant human serum albumin as an alternative to human plasma for patients with decompensated liver cirrhosis: a randomised, double-blind, positive-controlled and non-inferiority trial. *Gut* 2025; 74: 1476-1485. doi: 10.1136/gutjnl-2025-335577

Human albumin solution (HAS) is an essential therapy in decompensated cirrhosis. Despite the infectious risk and unacceptability in some cultures of using human products, plasma-derived human serum albumin (pHSA) remains the only source of HAS. Challenges in developing recombinant HSA (rHSA) include high costs and difficult scalability. Niu *et al.,* developed rHSA from rice grains of *Oryza sativa* (OsrHSA). Its proposed advantages include low immunogenicity, low costs and the relative ease of growing rice.

This phase II clinical trial (HY1001) evaluated the safety and efficacy of OsrHSA compared to pHSA in patients with decompensated cirrhosis, ascites and albumin level ≤30g/L. It was a randomised, double-blinded multicentre trial. Patients received daily infusions of OsrHSA or pHSA for up to 14 days and were followed up for two weeks.

Two hundred twenty-four patients were enrolled. There was no significant difference between the OsrHSA and pHSA groups in: proportion of patients reaching the primary endpoint (albumin ≥35g/L); time to endpoint; change in body weight/ascites. OsrHSA did not generate any anti-drug antibodies in the 20g group, and generated similar levels of anti-host cell protein antibodies as pHSA. Infusion-related adverse events were similar between OsrHSA and pHSA.

OsrHSA holds promise as an alternative to pHSA. Limitations of this trial include HAS being used outside internationally accepted indications (hepatorenal syndrome, spontaneous bacterial peritonitis and paracentesis); a short follow-up period; the exclusion of patients with known rice/cereal allergies; and the uncertain feasibility of producing this protein at the levels required to meet global demand.