patients. For those who needed DEXA scan, FRAX score was re-calculated using the T score for neck of femur in order to identify those needing treatment.

Results In 2016, a total of 51(40 male) cirrhotic patients were reviewed in the clinic (ALD 25, NASH 9, other 17). Other aetiologies included HCV, PBC and HFE-related cirrhosis. Only 3 patients had Child Pugh B7 with the rest having Child A disease. FRAX score identified (27) low risk, (22) intermediate risk and (2) high risk for major fracture. Most of the low risk group were treated with reassurance and life style advice although 2 patients required DEXA scan due to radiological evidence of osteopenia and one of them was commenced on treatment. BMD was measured in patients with intermediate risk and 9 required intervention as their post DEXA scan FRAX score showed higher fracture probability. High risk patients were considered for treatment immediately without waiting for DEXA scan (figure 1). In all the three groups, treatment was achieved by consulting our rheumatology team. Fractures during our clinic period were reported in one of the high risk cohort following a fall while another patient has accidental spine fracture findings in a routine CXR. There were no fractures in the low or intermediate group over the 5 year follow up period.

Conclusions Using the FRAX model in patients with cirrhosis shows promise in the identification of low risk patients who do not require DEXA scan.

P076

A MULTI-CENTRE, RANDOMIZED CONTROLLED STUDY, TO EVALUATE THE SAFETY AND PERFORMANCE OF THE DIALIVE LIVER DIALYSIS DEVICE IN PATIENTS WITH ACUTE ON CHRONIC LIVER FAILURE (ACLF) VERSUS STANDARD OF CARE (SOC) (ALIVER CONSORTIUM)

¹Banwari Agarwal*, ²Faouzi Saliba, ^{3,4}Dana Rodica Tomescu, ⁵Rafael Banares Canizares, ⁶Daniel Martin, ⁷Vanessa Stadlbauer, ^{8,1}Gavin Wright, ⁹Mohammed Sheikh, ¹⁰Carrie Morgan, ⁹Fausto Andreola, ⁹Lennart Oettl, ¹¹Carlos Alzola, ⁸Rahul Kumar, ²Sophie Caroline Sacleux, ⁶Gernot Schilcher, ¹²Sebastian Koball, ⁴Andrada Tudor, ¹³Jaak Minten, ¹⁴Gema Domenech, ¹⁴Juan Jose Aragones, ⁹Karl Oettl, ¹⁵Katja Waterstradt, ¹⁶Stefanie M Bode-Boger, ¹⁷Luis Ibanez, ¹Amir Gander, ^{12,18}Jan Stange, ¹⁹Moises Sanchez, ²⁰Rajeshwar P Mookerjee, ⁹Andrew Davenport, ²⁰Nathan Davies, ¹⁰Marco Pavesi, ²¹Javier Fernandez, ^{12,18}Steffen Mitzner, ¹⁰Vicente Arroyo, ⁸Rajiv Jalan. ¹Royal Free Hospital, UK; ²AP-HP Hôpital Paul Brousse, Centre Hépatobiliaire, INSERM unit N° 1193, Université Paris-Saclay, France; ³Carol Davila University of Medicine and Pharmacy, Romania; ⁴Fundeni Clinical Institute Bucharest, Romania; ⁵Hospital Gregorio Marañon, Spain; ⁶Peninsula Medical School, University of Plymouth, UK; ⁷Division of Gastroenterology and Hepatology Medical University of Graz, Austria; ⁸Basildon and Thurrock University Hospital, Mid and South Essex NHS Foundation Trust, Basildon, UK; ⁹University College London, UK; ¹⁰Yaqrit Ltd, UK; ¹¹Etera Solutions, US; ¹²University Hospital Rostock, Germany; ¹³Independent Clinical Research Organisation, Belgium; ¹⁴Medical Statistics Core Facility IDIBAPS – Hospital Clinic, Barcelona; ¹⁵MedInnovation GmbH, Germany; ¹⁶Institut für Klinische Pharmakologie Magdeburg, Germany; ¹⁷Department of Gastroenterology, Gregorio Marañon General University Hospital, Health Research Institute Gregorio Marañon, Complutense University of Madrid, Spain; ¹⁸Fraunhofer IZI, Germany; ¹⁹IBM, Ireland; ²⁰ILDH – University College London, UK; ²¹Liver ICU, Liver Unit, Hospital Clinic Barcelona, Spain; ²²Changi General Hospital, Singapore; ²³EF-CLIF, Barcelona

10.1136/gutjnl-2021-BASL.84

Background and Aims Treatment of ACLF is an unmet need. DIALIVE is a novel liver dialysis device that replaces dysfunctional albumin and removes PAMPs and DAMPs. This RCT tests the hypothesis that DIALIVE improves the prognosis of ACLF patients. Primary endpoint was safety, and other endpoints included clinical and pathophysiologic effects and device performance.

Method EUH2020 funded the RCT. Patients population had ACLF Grades 1–3a, and the main endpoints were evaluated at Day 10. For the patient to be evaluable, they had 3–5 DIALIVE sessions. No specific hypothesis was to be statistically assessed. 2-populations were defined: Safety: Patients having at least 1 DIALIVE treatment. Modified-safety (MS): Evaluable patients. A post-hoc inferential Mixed Models for Repeated Measurements analysis was performed to evaluate the differences between groups at Days 5 and 10. Log-rank and Wald tests were performed to assess ACLF resolution.

Results Study: 32-ACLF patients with alcoholic cirrhosis were randomised either to DIALIVE (N=17; 13M; age: 49 (12.4); CLIF-OFs: 10.3 (1.6); CLIF-C ACLFs: 48.6 (7.3)) or SOC (n=15; 13M; age: 49.1 (10.2); CLIF-OFs: 9.9 (1.2); CLIF-C ACLFs: 47 (6.5)). 30 patients (15 in each arm) comprised the MS set. DIALIVE was administered for a median of 3 sessions (range 1–5) in first 3-days (range 1–6) for a median of 8 hours (7–12) each day. Safety: 5 of 17 patients died in the DIALIVE group; 4 of 15 in SOC group. SAEs were seen in 64.7% in DIALIVE and 53.3% in the SOC group. Efficacy: CLIF-OF score: Significant improvement in the Liver (p=0.045) and Brain (p<0.001) subscores in DIALIVE; and deterioration of Lung subscore (p=0.002) in the SOC group (Day 10). This resulted in a significant overall treatment effect in CLIF-OFs (p=0.043). ACLF Grade: Significantly more cases reached ACLF 0 (33.3% vs 66.7%) favoring DIALIVE (logrank p=0.0357) and a 2.8x faster time to ACLF 0 (Wald test p=0.059) (figure 1). CLIF-C ACLF score: Difference of means (standard error) between DIALIVE and SOC at Day 10 was -5.4 (2.9) in favour of the DIALIVE group (p=0.064). MELD score: Significantly lower in DIALIVE at both Days 5 (p=0.049) and 10 (p=0.028) vs SOC.

Conclusions DIALIVE is safe and significantly increases proportion of patients resolving ACLF and reduces time to resolution. The data justify late phase clinical trials.

Abstract P076 Figure 1 This Kaplan Meier graph shows that significantly greater proportion of patients resolve ACLF with a faster resolution in the DIALIVE group