A Two-part Study to Investigate the Effects in Adults of Two Doses of Golexanolone in Patients With Primary Biliary Cholangitis (PBC) With Fatigue and Cognitive Dysfunction

NCT07304843

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Umecrine Cognition AB
Enrollment	84 participants

Key Eligibility Criteria

Inclusion (11)

- Male and female subjects age e 18 years
- Diagnosis of PBC based on the presence of e2 of 3 key disease characteristics
- Clinically significant fatigue defined for the purposes of this study as a PBC-40 fatigue domain score of e29 at screening
- Clinically significant cognitive symptoms, defined for the purposes of this study as a PBC-40 cognitive domain e16 at screening
- Stable PBC SoC therapy (if any),for at least 3 months prior to randomisation

... and 6 more (see full listing online)

Exclusion (25)

- Child-Pugh class B or C cirrhosis
- Clinical evidence of hepatic decompensation (e.g. current or prior HE, ascites, or variceal bleeding)
- History of hepatocellular carcinoma
- Bilirubin \>1.5 x ULN
- Glomerular filtration rate (GFR) \<35 mL/min/1.73m2

... and 20 more (see full listing online)

Locations (36 total)

University Hospital Düsseldorf, Düsseldorf, Germany
University of Leipzig, Leipzig, Germany
Hippokration General Hospital of Athens, Athens, Greece
... and 33 more locations