A Study to Assess the Genetic Variations in Bile Flow Disorders: Linking Progressive Familial Intrahepatic Cholestasis (PFIC)-Related Genes to Symptoms in Adults With Recurrent Cholestasis in Spain

NCT07191704

Status	RECRUITING
Sponsor	Ipsen
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (3)

- Adult patients (e18 years old) with written informed consent prior to data collection and study procedures.
- Unexplained recurrent and/or chronic cholestasis (idiopathic cholestasis), defined as alkaline phosphatase (ALP) or Gamma-Glutamyl Transferase (GGT) \> Upper Limit of Normal (ULN).
- Patients who provide the blood sample for the genetic analysis.

Exclusion (5)

- Patients with clear and confirmed diagnosed causes of cholestasis, including:
- Primary Biliary Cholangitis
- Primary or Secondary Sclerosing Cholangitis
- Obstruction of the bile ducts
- Other Liver diseases: cholestasis secondary to hepatocellular injury, viral hepatitis (mainly Hepatitis A virus \[HAV\], Hepatitis B virus \[HBV\] and Hepatitis C virus \[HCV\]), toxic hepatitis (pharmacological; drug-induced liver injury \[DILI\]), autoimmune hepatitis; intestinal failure, total parenteral nutrition \[TPN\]; Wilson's disease, choledochal cyst, Caroli Syndrome, and thick bile due to haemolysis.

Locations (10 total)

H. Clinic (first CEIm), Barcelona, Spain
H. Vall Hebron, Barcelona, Spain
H. Reina Sofía, Córdoba, Spain
... and 7 more locations