

Hepatic Impairment With Cirrhosis Due to Cholestatic Liver Disease

NCT05045482

Status	RECRUITING
Phase	Phase 1
Sponsor	Zydus Therapeutics Inc.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (18)

- For all subjects:
- Ability to comprehend and willingness to sign a written ICF for the study.
- Male or female aged 18 to 80 years (inclusive) at the time of signing the ICF.
- Body mass index within the range 18.0 to 48.0 kg/m² (inclusive) at screening.
- Females must be non-pregnant, non-lactating and of non-childbearing potential or using highly efficient contraception for the full duration of the study.

... and 13 more (see full listing online)

Exclusion (28)

- For all subjects:
- Any significant, unstable medical condition or other instability that would prevent the subject from participating in the study as determined by the Investigator or designee.
- History of malignancy of any type in the last 3 years of screening, with the exception of the following: in situ cervical or breast cancer or surgically excised non-melanoma skin cancers (i.e. basal cell or squamous cell carcinoma).
- History of stomach or intestinal surgery or resection within the six months prior to screening that would potentially alter absorption and/or excretion of orally administered drugs (uncomplicated appendectomy, cholecystectomy, and hernia repair will be allowed).
- History of any significant drug allergy (such as anaphylaxis) deemed clinically relevant by the Investigator.

... and 23 more (see full listing online)

Locations (1 total)

Zydus US002, Indianapolis, Indiana, United States