

Study of ADI-PEG 20 Versus Placebo in Subjects With NASH

NCT05842512

Status	RECRUITING
Phase	Phase 2
Sponsor	Polaris Group
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (25)

- Males and non-lactating, pregnancy test negative females between 18 - 80 years of age with biopsy proven F1 - F4 (compensated cirrhosis, Child-Pugh A, score d6) NASH. Limit F1 fibrosis to d 20% of total subject population.
- Willingness to use appropriate contraceptive measures throughout study treatment and for 90 days thereafter (see Appendix A).
- Body mass index (BMI) \geq 23 kg/m²
- Must have confirmation of \leq 5 % liver fat content on MRI-PDFF at screening.
- Biopsy-proven NASH confirmed by a central pathologist. Must have had a liver biopsy either during the screening period or a historical biopsy conducted within the last 6 months prior to pre-screening with fibrosis stage 1 to 4 (F score, F1-F4) and a non-alcoholic fatty liver disease (NAFLD) activity score (NAS) of \leq 4 with at least a score of 1 in each of the following NAS components:

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

Exclusion (19)

- Weight gain or loss \geq 5% in the 3 months prior to randomization or \geq 10% in the 6 months prior to screening.
- Type 1 and insulin-dependent Type 2 diabetes.
- Poorly controlled hypertension (blood pressure [BP] \geq 160/100 mmHg).
- Prior history of decompensated liver disease including ascites, hepatic encephalopathy (HE), or variceal bleeding.
- Chronic hepatitis B virus (HBV) infection (hepatitis B surface antigen [HBsAg] positive).

... and 14 more (see full listing online)

Locations (10 total)

Ditmanson Medical Foundation Chiayi Christian Hospital Chiayi Christian Hospital (CYCH), Chiayi City, Taiwan, Taiwan
Kaohsiung Medical University Chung-Ho Memorial Hospital(KMUH), Kaohsiung, Taiwan, Taiwan
E-Da Hospital (EDH), Kaohsiung, Taiwan, Taiwan

... and 7 more locations