

Nonalcoholic Fatty Liver Disease in HIV Database

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Documented HIV infection * ≥ 18 of age at time of initial screening * HIV suppression with HIV RNA < 200 copies/ml on stable ART for ≥ 6 months and no change in ART class for ≥ 3 months, prior to enrollment * Participants must meet at least one of the following inclusion criteria: * Histologically confirmed NAFLD [defined as NAFL ($> 5\%$ steatosis, with or without lobular or portal inflammation), borderline NASH or definitive NASH] within 6 months prior to screening (per local pathology report) * Liver stiffness measurement (LSM) ≥ 6 kPa from FibroScan exam performed during screening or within 12 months prior to screening and a diagnosis of NAFLD based on clinical and imaging (FibroScan CAP ≥ 263 dB/m, ultrasound, CT or MRI) diagnosis at any time * LSM ≥ 8 kPa from FibroScan exam performed during screening or within 12 months prior to screening, in the absence of CAP ≥ 263 dB/m * Able to provide written informed consent to part * Willingness to be in the study for 1 or more years * Provision of written informed consent

Exclusion Criteria:

* Positive hepatitis B surface antigen * Evidence of recent or current hepatitis C virus (HCV) as marked by the presence of anti-HCV antibody with detectable HCV RNA in serum within 3 years prior to enrollment. Participants with anti-HCV antibody positivity who have undetectable HCV RNA 3 years prior to enrollment (either due to spontaneous clearance or clearance with treatment) will be eligible to participate if HCV RNA at entry remains undetected * Significant alcohol consumption (≥ 3 drinks daily on average in men and ≥ 2 drinks daily on average in women) * Evidence of other causes of chronic liver disease * History of prolonged (> 1 month) total parenteral nutrition within a 6-month period before liver biopsy or before baseline FibroScan VCTE exam * Short bowel syndrome * History of biliopancreatic diversion * History of bariatric surgery within 2 years of enrollment (participants expecting to undergo bariatric surgery can be enrolled prior to the procedure) * Solid organ transplant recipients * Other condition that is likely to interfere with study follow-up

Conditions & Interventions

Conditions:

NAFLD, NASH - Nonalcoholic Steatohepatitis, Hiv

More Information

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Phase: N/A

IRB

Number: HM20023554

System ID: NCT05023044

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