National Liver Cancer Screening Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 85 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

Patient must meet all of the following inclusion criteria: 1. Adult patients ages 18-85 with cirrhosis from any etiology or with chronic hepatitis B with a PAGE-B score greater than 9 within 12 months of enrollment 2. Patient is eligible for HCC surveillance according to treating physician or by the site investigator 3. Able to provide informed consent 4. Life expectancy \>6 months (after consent) as determined by the treating provider or site investigator

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Exclusion Criteria:

Patient will be excluded for any of the following exclusion criteria: 1. Child Pugh C cirrhosis 2. History or clinical symptoms of hepatocellular carcinoma or cholangiocarcinoma 3. History of solid nodule on baseline ultrasound (i.e., lesion 1cm or greater) within 9 months prior to consent without subsequent diagnostic CT/MRI demonstrating benign nature) 4. AFP \>20 ng/mL within 6 months prior to consent, in the absence of a contrast-enhanced CT or MRI within 6 months of AFP (before or after) level demonstrating lack of suspicious liver lesions 5. Newly diagnosed LR-3 greater than or equal to 1 cm within 6 months prior to consent 6. History of LR-4, LR-5, or LR-M on multi-phase CT or contrast-enhanced MRI within 6 months prior to consent 7. Presence of another active cancer besides non-melanomatous skin cancer or indolent cancer under active surveillance (e.g., prostate cancer or renal cell carcinoma) within the 2 years prior to consent 8. Patient's provider is planning to use MRI- or CT- based surveillance moving forward 9. History of a transjugular intrahepatic portosystemic shunt (TIPS) 10. History of Fontan associated liver disease or cardiac cirrhosis 11. History of solid organ transplantation 12. Actively listed for liver transplantation 13. Diagnosis of alcohol-associated hepatitis within 3 months prior to consent 14. Documented current or continued signs and symptoms of acute Wilson disease (acute liver failure, acute neurological deficits, hemolysis) 15. In patients with primary sclerosing cholangitis (PSC): Current active cholangitis within 90 days prior to consent 16. Known or documented habitual non-adherence to previous research studies or medical procedures or unwillingness to adhere to protocol (e.g., unwilling to obtain consent or samples) 17. In patients living with HIV: CD4+ T cell count less than 100 cells/mm3 within 60 days prior to consent 18. Known pregnancy at consent 19. Active warfarin use

Conditions & Interventions

Interventions:
DIAGNOSTIC_TEST: GALAD, DIAGNOSTIC_TEST: Liver Ultrasound with or without AFP
Conditions:
Carcinoma, Hepatocellular, Liver Cancer, Liver Cirrhosis, Hepatitis B
Keywords:
Hepatocellular carcinoma surveillance, GALAD, Alpha Fetoprotein

More Information

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Number:
System ID: NCT06084234
