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Sulfation of Bile Acids as a Biomarker for Hepatobiliary Diseases

ClinicalTrials.gov Identifier: NCT01200082

Recruitment Status : Recruiting
First Posted : September 13, 2010
Last Update Posted : June 17, 2020

See **Contacts and Locations**

Sponsor:
University of Nebraska

Information provided by (Responsible Party):

Yazen **Alnouti**, University of Nebraska

Study Description

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Brief Summary:

The investigators hypothesize that the extent of sulfation of toxic BAs and their urinary elimination can be used as a biomarker to predict the severity and prognosis of hepatobiliary diseases. The investigators rationale in this project is that the discovery of biomarkers specific to liver injury would provide the foundation for a specific and non-invasive tool to evaluate disease prognosis, determine patients with higher risk of developing end-stage liver diseases, and determine patients with higher risk of recurrence of hepatobiliary complications after liver transplant.

Patients on the liver transplant list are continuously monitored during their hospitalization and are scheduled for follow-up visits for 12 months after their release post-surgery. Disease progression will be evaluated by monitoring MELD scores, survival, incidence of liver transplant, and incidence of complications related to hepatobiliary conditions such as fluid retention, GI bleeding, encephalopathy, and biliary stricture complications.

Condition or disease
Hepatobiliary Diseases

Detailed Description:

The investigators propose the following specific aims to test the investigators hypothesis:

Specific Aim #1: Establish a baseline of individual and total urinary BAs and BA-sulfates in healthy controls and patients with hepatobiliary diseases. A baseline reference of the average and distribution of the percentage of urinary BA-sulfates will be determined in healthy subjects and in patients with hepatobiliary diseases including chronic hepatitis C/B, alcoholic liver disease, hereditary, drug-induced, and autoimmune hepatobiliary diseases. The investigators working hypothesis is that patients' capability to sulfate total or specific BAs, as determined by the percentage of total or specific BAs excreted in the sulfate form, can predict the severity of hepatobiliary diseases, as determined by mayo model for end-stage liver disease (MELD) score and compensation status(compensated and decompensated). Patients with higher MELD score are considered to be at higher risk of developing severe hepatobiliary complications.

Specific Aim #2: Determine the relationship between BA sulfation and the progression of hepatobiliary diseases. This is an exploratory aim to collect preliminary data on the relationship between urinary BAs and the progression of hepatobiliary diseases in liver-transplant and non-liver-transplant patients, as monitored over a1-year period. The investigators working hypothesis is that patients' capabilities of sulfating BAs determine the progression of the disease.

Study Design

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Study Type :	Observational
Estimated Enrollment :	400 participants
Observational Model:	Cohort
Time Perspective:	Prospective
Official Title:	Sulfation of Bile Acids as a Biomarker for Hepatobiliary Diseases
Actual Study Start Date :	November 2011
Estimated Primary Completion Date :	December 31, 2021
Estimated Study Completion Date :	December 31, 2021

Resource links provided by the National Library of Medicine NIH NLM

MedlinePlus related topics: Liver Diseases

Genetic and Rare Diseases Information Center resources:
Progressive Familial Intrahepatic Cholestasis 1
Primary Sclerosing Cholangitis Primary Biliary Cholangitis

U.S. FDA Resources

Groups and Cohorts

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Group/Cohort
Healthy Controls Male or female, age 19-65, no apparent signs of hepatobiliary diseases
Patients with hepatobiliary diseases Male or female, age 19-65, visiting the UNMC hepatology clinic for treatment from hepatobiliary diseases

Outcome Measures

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Primary Outcome Measures :

1. Urinary bile acid indexes [Time Frame: Healthy controls: 4 visits over 28 days. Patients: urine collction at every visit as decided in their course of treatment]

   Bile acids (BAs), the end products of cholesterol metabolism, are synthesized in liver and excreted into bile, which flows to the small intestine via the bile duct. Most of the BAs are reabsorbed from the intestine into the portal circulation and undergo enterohepatic recirculation with minimal levels detected in urine and blood under normal conditions.

Secondary Outcome Measures :

1. mayo model for end-stage liver disease score (MELD) [Time Frame: Healthy controls: 1st visit only (1 week). Patients: every time a MELD score is required by hepatologists as partrt of their regular course of treatment (1 year)]

   MELD score= 3.8*loge (bilirubin [mg/dL]) + 11.2*loge (INR) + 9.6*loge (creatinine [mg/dL]).

Biospecimen Retention: Samples Without DNA

lood samples will be collected from healthy volunteers at their 1st visit. Urine samples will be obtained from healthy controntrols and patients with hepatobiliary diseases over time.

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 19 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Sampling Method: Non-Probability Sample

Study Population

Healthy Controls: Subjects with no apparemt hepatobiliary diseases Patient Populaton: Subjects visiting the hepatology clinic in UNMC as part of their treatment of hepatobiliry diseases

Criteria

Healthy Controls

Inclusion Criteria:

- Male or female, age 19-65, no apparent signs of hepatobiliary diseases

Exclusion Criteria:

- Levels higher than 50, 56, 78 U/L for ALT, AST, and GGT, respectively.

Patient Population

Inclusion Criteria:

- Male or female, age 19-65, visiting the UNMC hepatology clinic for treatment from hepatobiliary diseases

Exclusion Criteria:

- MELD score less than 6

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01200082***

Contacts

Contact: Yazen M **Alnouti**, Ph.D 402-559-4631 yalnouti@unmc.edu

Locations

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Sponsors and Collaborators

University of Nebraska

Investigators

Principal Investigator: Yazen M **Alnouti**, Ph.D University of Nebraska

More Information

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Publications:

Simko V, Michael S. Urinary bile acids in population screening for inapparent liver disease. Hepatogastroenterology. 1998 Sep-Oct;45(23):1706-14.

Makino I, Hashimoto H, Shinozaki K, Yoshino K, Nakagawa S. Sulfated and nonsulfated bile acids in urine, serum, and bile of patients with hepatobiliary diseases. Gastroenterology. 1975 Mar;68(3):545-53.

Almé B, Bremmelgaard A, Sjövall J, Thomassen P. Analysis of metabolic profiles of bile acids in urine using a lipophilic anion exchanger and computerized gas-liquid chromatorgaphy-mass spectrometry. J Lipid Res. 1977 May;18(3):339-62.

Responsible Party:	Yazen **Alnouti**, Principal Investigator, University of Nebraska
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Other Study ID Numbers:	487-10-EP
First Posted:	September 13, 2010 Key Record Dates
Last Update Posted:	June 17, 2020
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Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Yazen **Alnouti**, University of Nebraska:
chronic hepatitis C/B
alcoholic liver disease
primary biliary cirrhosis

primary sclerosing cholangitis
progressive familial intrahepatic cholestasis

Additional relevant MeSH terms:
Liver Diseases
Digestive System Diseases