

## MRI Biomarkers in as Predictor of Clinical Endpoints in Pediatric Autoimmune Liver Disease

Status: RECRUITING

### Eligibility Criteria

Sex: ALL

Age: 6 years to 23 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Age 6-23 years old.
2. Established clinical diagnosis of AIH or PSC.

Exclusion Criteria:

1. History of liver transplantation.
2. Chronic Hepatitis B or untreated hepatitis C virus infection.
3. Pregnancy.
4. Absolute contraindication for MRI (e.g. pacemaker, metallic implants, claustrophobia).
5. Diagnosis of cystic fibrosis or biliary atresia
6. Diagnosis of cardiac hepatopathy.
7. Diagnosis of Wilson's disease, Alpha-1 Antitrypsin deficiency, or Glycogen storage disease.
8. Skin conditions which could be aggravated by MREL (i.e. Epidermolysis bullosa).

### Conditions & Interventions

Conditions:

Autoimmune Liver Disease, Autoimmune Hepatitis, Primary Sclerosing Cholangitis

### More Information

Description:

Autoimmune liver diseases (AILD), which include Primary Sclerosing Cholangitis (PSC) and Autoimmune Hepatitis (AIH) are a common etiological factor for chronic liver disease among adolescents. This is a longitudinal study to identify surrogate endpoints with an accurate predictive value for the progression of hepatobiliary damage in subjects with pediatric onset AILD. This study will involve collection of MRI-based data at the time of enrollment and at year 1 and 2 of follow up, and collection of clinical data for 10 years following enrollment. There is a strong possibility that MRI quantitative techniques may be more sensitive to disease progression than standard clinical and laboratory tests. To investigate predictivity of MRI based biomarkers, summary measures of MRCP/MREL from baseline, Year 1 and Year 2, e.g. change rate, maximum, and average will be calculated as predictors for Year 10 clinical outcomes. The same predictors will also be used to model native liver survival in a proportional hazard regression. Findings from this study may be used to assess disease progression and to predict complications and survival of liver disease patients.

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Principal Investigator ID:

Phase:

IRB Number:

System ID: NCT03178630

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