Early Signals of the Transition From Immune Quiescence to Activation in the Liver Allograft Microenvironment and in the Circulation

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years to 13 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and parent or guardian must be able to understand and provide informed assent and consent, respectively
2. Recipient of a living or deceased donor Liver transplant (LTx) at <7 years of age
3. > 3 years but <7 years after LTx at the time of study enrollment
4. Stable liver tests defined as baseline serum alanine aminotransferase (ALT) level < 30 IU/l and gamma-glutamyl transferase (GGT) level < 50 IU/l (based on the average of the 3 most recent values prior to screening; all must be within 1 year of screening; 2 must be within 6 months of screening)
5. No Acute rejection (AR) or chronic rejection within 12 months of enrollment
6. Tacrolimus monotherapy for > 6 months with baseline 12-hour trough levels <8 ng/mL (based on the average of 3 values prior to screening; all must be within 1 year of screening; 2 must be within 6 months of screening)
7. Participants of childbearing potential must have a negative pregnancy test upon study entry

Exclusion Criteria:

1. Liver transplant (LTx) for autoimmune disease, including autoimmune hepatitis or primary sclerosing cholangitis
2. LTx for hepatitis B or hepatitis C
3. Recipient of any other organ transplant or liver re-transplant, except for patients who have a repeat LTx within 30 days of first LTx who are eligible for enrollment
4. >=50 percent dose increase in tacrolimus within 12 months of enrollment
5. Discontinued a second Immunosuppression (IS) agent within 12 months of enrollment
6. Systemic illness requiring chronic or recurrent use of IS for which there is a risk of reactivation if tacrolimus is reduced
7. Use of medication to treat systemic conditions which in the judgement of the investigator could influence results of the study
8. Active or chronic infection requiring treatment
9. Inability or unwillingness to comply with the study protocol
10. Use of investigational drug within 4 weeks (or 5 half-lives of investigational drug, whichever is longer) of enrollment
11. Has any condition that, in the opinion of the investigator, will interfere with safe participation in the trial

Conditions & Interventions

Interventions:
DRUG: Immunosuppression Reduction
Conditions:
Liver Transplant
Keywords:
Liver transplant, Immunosuppression

More Information

Description:
This is a prospective multi-center, longitudinal study to determine efficacy of 50 percent Immunosuppression (IS) reduction. One hundred fully eligible participants will reduce IS by 50 percent in two steps. Liver tests will be checked every 0.5 months through month 4, once a month through month 12, and every other month through month 18. Liver transplant (LTx) center visits will take place at screening, months 6, 12 and 18 after initiating IS dose reduction. A protocol driven liver biopsy to adjudicate the endpoint will be performed at 18 months. The duration of the study from time of starting IS dose reduction to the primary endpoint assessment is 18 months. The primary objective is to assess the efficacy of 50 percent IS dose reduction in children with Liver transplants (LTxs)

Contact(s): Erin Chapman - Erin.Chapman@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT07549503

Thank you for choosing StudyFinder. Please visit http://studyfinder.cchmc.org to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.