# New Study

## Looking at immunosuppression withdrawal in Liver transplant Patients

### Inclusion Criteria

1. At the time of screening: more than 3 years post-transplant if participants are ≥50 years old, OR ≥ 6 years post-transplant if participant age is 18-49 years old.

2. Recipient of either deceased or living donor liver transplant.

3. Recipient of single organ transplant only

4. Liver function tests: direct bilirubin ≤17.1 umol/L and ALT ≤60 IU/L at the screening visit.

5. On calcineurin inhibitor (CNI) based maintenance IS and no more than one of the following: Low dose mycophenolic acid (≤ 1080 mg daily), mycophenolate mofetil (MMF ≤ 1500 mg daily), or azathioprine (≤ 150 mg daily); or on mycophenolate/mycophenolic acid monotherapy (effective contraception must be used before beginning mycophenolate therapy, during therapy, and for six weeks following discontinuation of therapy).

6. Ability to sign informed consent

### Exclusion Criteria

1. Serum positivity for HCV-RNA

2. Serum positivity for HIV-1 infection, HBV surface antigen or HBV-DNA

3. Immune-mediated liver disease in which IS discontinuation is inadvisable (autoimmune hepatitis, primary sclerosing cholangitis, primary biliary cirrhosis).

4. Acute or chronic rejection within the 52 weeks prior to screening.

5. GFR <40 mL/min (to mitigate the risk of worsening renal failure should rejection occur and high level of CNI be required).

6. The need for chronic anti-coagulation that cannot be safely discontinued to safely perform for a liver biopsy.

7. Baseline (screening) liver biopsy showing any of the following: a) acute rejection according to Banff criteria; b) early or late chronic rejection according to Banff criteria; c) inflammatory activity and/or fibrosis in excess of permissive criteria (Table 1) (25); f) any other findings that might make participation in the trial unsafe. Eligibility will be determined by the central pathologist.

8. Patient age <18 years old at the time of transplant.

9. Pregnant females and females of childbearing age not using effective contraception.

10. Current illicit drug or alcohol abuse.

11. Inability to participate in frequent monitoring of liver function (every 3 weeks) and clinical visits during IS withdrawal.

12. Inability to comply with study directed treatment.

13. Any medical condition that in the opinion of the principal investigator would interfere with safe completion of the trial.

14. Participation in another clinical trial during the month prior to enrolment

**About the study**

The Cambridge Liver Transplant Unit has been selected to join a national and international study looking at reducing and then withdrawing immune suppression medication in a small number of highly selected liver transplant recipients.

The objectives of the study are to see first if this approach is safe and then to examine the impact on the quality of life and health-economics in those able to continue without immune suppression.

The study involves at least 11 visits to Addenbrooke's Hospital over 4 years and they need to have as many as 3 liver biopsies. There will be additional telephone follow-up for some patients.

Selective patients have been given a letter inviting them to participate in the study they may bring this with them for their clinic visit.

If you require further information please contact:

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