Selected eligibility criteria

Males and females, aged 18 to 75 years

Diagnosis of large duct ('classical') PSC via MRCP/ERCP, for more than 24 weeks

ALP level must be at least 1.5 times the upper limit of the normal range.

Stable or no Inflammatory bowel disease

Stable doses of any other medications you take for at least the past 12 weeks

For those receiving UDCA (ursodeoxycholic acid), the dose must be stable for at least the past 12 weeks and must be 23 mg/kg/day or less

No evidence or history or suspicion of bile duct cancer (cholangiocarcinoma)

Patients who have had stents or balloon dilation in the bile ducts should have been stable for at least the past 24 weeks

No clinically significant changes in liver transaminase levels on repeated measures (screening & randomization)

No cholangitis during the last 90 days

Patients with portal hypertension should not have had complications

No malignancy (cancer) diagnosed in the last 3 years (except adequately treated non-metastatic basal and squamous cell skin cancers or cervical carcinoma in situ)

No chronic hepatitis B or C infection

If you meet these criteria, you might be suitable to take part in the SPRING Study.

Ver. 1.0, 09Feb2021

Chemomab THERAPEUTICS

For further information and study site locations:
NIH number: NCT04595825

www.chemomab.com/trials/psc/

PSC Support

Patient associations:
www.pscsupport.org.uk/spring

www.hetzliver.org

Chemomab THERAPEUTICS

CM-101 A Novel Treatment for PSC

The SPRING Phase 2 study

About Primary sclerosing cholangitis (PSC)

PSC is a rare, immune-mediated and long-term progressive disease which results in inflammation and scarring (fibrosis) in the liver and bile ducts. It commonly affects people with inflammatory bowel disease. Affected individuals may have no symptoms or may experience signs and symptoms of liver disease such as yellow discoloration of the skin and eyes, itching, and abdominal pain.

The inflammation and scarring in the bile ducts indicate that the bile ducts become narrow and sometimes blocked. This means that the bile, which normally flows from the liver into the intestines, cannot flow as easily. This can eventually lead to scarring in the liver (cirrhosis) and liver failure. PSC increases the risk of various cancers including liver, bile ducts and gallbladder cancers. The underlying cause of PSC is unknown. It is thought that genetic susceptibility, immune system dysfunction, and an altered composition of the bacteria in the gut may play a role.

There is no effective medical treatment for PSC. Many people affected by PSC require a liver transplant.

About CCL24 & CM-101

CCL24 is a small protein involved in cell "communication" that helps promote inflammation and is involved in the development of scarring tissue (fibrosis). CCL24 is found in higher concentrations in PSC patients than the general population.

CM-101 is a monoclonal antibody that can interfere with the actions of CCL24 and thus its role in the development of inflammation and fibrosis. CM-101 was tested in several animal models, including the MDR2 knockout mice (mice that have severe fibrosis and cirrhosis in the liver and bile ducts). These tests showed that CM-101 significantly reduced liver fibrosis, and markers that indicate the presence of inflammation in the bile ducts. CM-101 was also tested in early human trials in healthy volunteers and patients with non-alcoholic fatty liver disease (NAFLD). 67 to 75% of NAFLD patients who were treated with CM-101 experienced an improvement in markers of fibrosis.

The SPRING Study

SPRING is a 6-month Phase 2a clinical trial in the UK and Israel, evaluating CM-101 in PSC patients, sponsored by Chemomab.

People who are interested in taking part in this clinical trial will undergo some screening tests to make sure they are suitable for the trial before taking part. Those who are suitable, will be randomly allocated to receive treatment that is either the active drug CM-101, or a placebo (an inactive, 'dummy' drug). Participants will have a treatment, once every 3 weeks for 12 weeks. There will then be 15-weeks of safety follow-up.