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The use of CARBALIVE in the treatment of cholestatic liver disease

Submission date
09/10/2025

Recruitment status
No longer recruiting

Registration date
14/10/2025

Overall study status
Completed

Last Edited
13/10/2025

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Everyone has bacteria in their gut, but in healthy people, these bacteria normally remain confined in the gut. However, in people with primary sclerosing cholangitis (PSC), the types of bacteria in the gut are different compared to individuals without PSC. In PSC, gut bacteria leak from the gut and travel to the liver, where they can cause inflammation. Over time, this inflammation can lead to liver scarring. Ongoing leak of gut bacteria (and their fragments) can cause the liver to lose function and fail. When this happens, a liver transplant is needed.

This clinical trial will test a new way to lower the leakage of bacterial fragments with a new product called CARBALIVE (or Yaq-001). CARBALIVE works by directly binding to the bacterial fragments in the gut and preventing them from leaking and travelling to the liver. CARBALIVE is a new type of carbon which is being developed by the company Yaqrit Ltd. In animal experiments, the researchers have shown that CARBALIVE can bind harmful bacterial toxins. CARBALIVE, along with the bacterial toxins, are eliminated with stool without being absorbed into the bloodstream. This has been shown to have beneficial effects in animal models of liver disease and in humans who have advanced liver disease (cirrhosis) from causes other than PSC.

The purpose of this clinical trial is to see if the same effect is seen, specifically in people who have PSC. The goal of the trial is to assess if treatment with CARBALIVE is safe and is well-tolerated. Additionally, it will assess if CARBALIVE helps to improve overall health status.

Who can participate?
A total of 12 patients from The Queen Elizabeth Hospital, Birmingham, University Hospitals Birmingham NHS Trust will participate in this clinical trial. The study aims to recruit patients with a diagnosis of PSC as well as inflammatory bowel disease with evidence of moderate to advanced fibrosis in the liver.

What does the study involve?
Participants who agree to take part in the study, following review of the patient information sheet, will be invited for a screening visit. At this visit, participants will be asked to sign and date a consent form and undergo a general evaluation, including:

- Review of their medical history and medication history
- Physical examination
- Vital signs: blood pressure, pulse rate, respiratory rate, and body temperature
- Sample collection, to include blood, stool and urine

Once results are back and eligibility to participate in the study is confirmed, participants will attend their first treatment visit. The first six participants included in the study will receive a daily dose of 8g CARBALIVE. The second group of six participants will receive a daily dose of 12g CARBALIVE. The safety and tolerability of CARBALIVE will be assessed at two different dosages. People will start on the higher dose after the safety information is available about the 8g dose group.

Participants will be treated for 12 weeks. During this period, they will be assessed at week 6 and then week 12 of treatment. The following assessments will be performed at week 1 (on the first day you receive treatment), week 6 and week 12:

- Physical examination
- Vital signs: blood pressure, pulse rate, respiratory rate, and body temperature
- Collection of blood and urine samples for analysis at the hospital laboratory
- Review of changes in medical status since the previous visit
- Review of changes in medications taken since the previous visit

A blood sample will be drawn at each visit. Participants will also be asked to provide a stool sample. The stool sample can be obtained at home, up to 24 hours before attending the study visit. Specific containers for collecting stool samples will be provided.

Each study visit during the treatment period is anticipated to last 60 minutes. At each visit, the study doctor or study nurse will also ask you to complete a health-related quality of life questionnaire.
The study treatment will be supplied as sachets to be taken by mouth. The study team will provide instructions on how to take the treatment.

Participation in the study is completed at week 12, whereby similar assessments will be performed and samples collected.

What are the possible benefits and risks of participating?
Participation in the study is entirely voluntary. While there is no specific benefit to participants, the collective benefit is in participating in the study and helping progress our understanding of this disease and the effect of this treatment on PSC.

The study is associated with small risks. These include risks associated with taking blood samples, including pain, temporary dizziness and bruising. There may possibly be other side effects and risks that are currently unknown. If you are concerned about other, unknown side effects, please discuss this with the researchers.

Potential side effects related to the treatment include nausea, vomiting, constipation and diarrhoea (at a rate of less than 5%). Medication to counter these can be prescribed by the research doctor. There is a possibility that the carbons may bind and affect other medications that participants may be taking. The research team will instruct participants as to when to take other medications to prevent any possible interactions with CARBALIVE.

Because CARBALIVE is a very good adsorbent, there is a small possibility that some of the participants' vitamin levels will go down slightly, and they may need to take supplements during

the study. The team will monitor participants' vitamin levels, as part of their blood tests, throughout the study to make sure these are replaced as needed.

Where is the study run from?
The Queen Elizabeth Hospital Birmingham, University Hospitals Birmingham NHS Foundation Trust, UK.

When is the study starting and how long is it expected to run for?
June 2025 to August 2026. The study has received ethics approval from the HRA and Health and Care Research Wales (HCRW) and is set up to commence recruitment in October 2025. Recruitment will continue for 10 months.

Who is funding the study?
LifeArc Ltd

Who is the main contact?
Prof Palak Trivedi, CATChtrial@uhb.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
347693

Study information

Scientific Title
An open-label trial of CARBALIVE for the treatment of cholestatic liver disease

Acronym
CATCh Trial

Study objectives
The primary objective of this study is to determine the safety and tolerability of two doses (8g and 12g) of once daily, orally administered Yaq-001 (henceforth known as CARBALIVE) over 12 weeks, in patients with primary sclerosing cholangitis, who have moderate-advanced fibrosis and compensated liver disease.

The study also aims to explore the following secondary and translational objectives:

Secondary objectives:
• Routine liver laboratory parameters
• Patient-reported outcome (PRO) measures
• Surrogate biomarkers of liver fibrosis
• PSC-specific prognostic scores
• Inflammatory bowel disease (IBD) activity
• Incidence of trial endpoint events: cholangiocarcinoma / hepatopancreatobiliary malignancy, referral for liver transplantation, colonic resection or colorectal cancer, and/or mortality

Translational objectives:
To identify metagenomic, metatranscriptomic, and metabolomic signatures associated with biochemical and clinical response following CARBALIVE administration.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/06/2025, HRA and Health and Care Research Wales (HCRW) (2 Redman Place, Stratford, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8029; southbirmingham.rec@hra.nhs.uk), ref: 25/WM/0051

Primary study design
Interventional

Study design
Phase IIa single-centre open-label sequential-cohort-dosing clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The study is looking at patients with primary sclerosing cholangitis and co-existant inflammatory bowel disease.

Interventions
Yaq-001, commercially known as CARBALIVE, is a highly adsorbent activated carbon with tailored pore size distribution. The study will be investigating the safety and tolerability of two different doses of orally administered CARBALIVE (8g and 12 g) once a day for 12 weeks. This is a non-blinded sequential dosing study; therefore, randomisation is not applicable. The first 6 participants enrolled will receive the 8g dose, and the subsequent 6 will receive the 12g dose.

Intervention Type

Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
Yaq-001 (CARBALIVE)

Primary outcome(s)
Occurrence of adverse events as measured by CTCAE v5.0, alongside the incidence of adverse events of special interest: acute cholangitis flares (including those that are resistant to a single course of antibiotic treatment), acute colitis flares and episodes/time to hepatic decompensation over the 12-week treatment period.

Key secondary outcome(s)
The following secondary outcome measures will analyse the effects of CARBALIVE on markers of disease activity and severity throughout the course of the trial as measured at week 1, 6 and 12:
1. Liver function tests, including serum alkaline phosphatase (ALP), alanine transaminase (ALT), aspartate aminotransferase (AST), gamma glutamyl transferase, bilirubin, albumin and C-reactive protein
2. Surrogate biomarkers of liver fibrosis measured using the serum enhanced liver fibrosis score
3. Immune response indicators measured using circulating white blood cell count and platelet count
4. Patient-reported outcome (PRO) measures, using the following scores: simple cholestatic complaints score (SCCS), 5D itch, partial Mayo colitis score and SIBDQ
5. PSC-specific prognostic score measured using the Amsterdam-Oxford PSC score
6. IBD activity assessed using faecal calprotectin
7. Incidence of trial endpoint events, by recording the incidence of the following events: cholangiocarcinoma/hepatopancreatobiliary malignancy, referral for liver transplantation, colonic resection or colorectal cancer, and/or mortality

Completion date
13/08/2026

Eligibility

Key inclusion criteria
1. Written informed consent
2. Men and women age =/>16 years
3. Participants must be able to understand and comply with the purpose and procedures that are involved in the trial
4. An established diagnosis of colonic inflammatory bowel disease, with evident willingness to participate in an annual colonoscopic surveillance program, as per the routine standard of care
5. An established clinical diagnosis of large duct PSC, with compatible features as assessed by magnetic resonance cholangiopancreatography (MRCP) or endoscopic retrograde cholangiopancreatography (ERCP)
6. Evidence of moderate to advanced stage liver fibrosis, as suspected by any of the following:
6.1. Median vibration-controlled transient elastography score (VCTE) score of >9.5Pa, with an interquartile range ≤30%
6.2. Previous liver biopsy indicating at least moderate fibrosis (Ishak fibrosis stage >III, or

equivalent)
6.3. Serum enhanced liver fibrosis score (ELF) >7.7
6.4. Presence of portal hypertension (investigator discretion)
6.5. A colonoscopy showing no evidence of dysplasia/neoplasia within 24 months before screening
6.6. No evidence of active colitis, as evidenced by a Partial Mayo Score of ≤4, with a score of <2 on the rectal bleeding domain at screening
7. Individuals with IBD who are receiving treatment with biologics, immunosuppression or corticosteroids must be taking a stable dose for at least twelve weeks before screening, and be expected to remain on the same medication/same dose for the duration of the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. Secondary causes of sclerosing cholangitis including, but not limited to, IgG4-related cholangitis, cholangiopathy due to acquired immunodeficiency syndrome, drug-induced sclerosing cholangitis, trauma, ischaemic cholangiopathy, choledocholithiasis (investigator discretion), or sclerosing cholangiopathy as a sequela of hepatopancreatobiliary resection.
2. Other causes of liver disease, including, but not limited to, IgG4-related disease; viral hepatitis; alcohol-related liver disease; metabolic dysfunction-associated steatotic liver disease; drug-induced liver disease; autoimmune hepatitis; hereditary haemochromatosis; alpha-1-antitrypsin disease; primary biliary cholangitis; Wilson disease; Budd-Chiari Syndrome; or primary or secondary hepatopancreatobiliary cancer.
3. Presence of a clinically significant dominant stricture based on the combination of radiological, biochemical and clinical features. Patients can be included in the trial with a dominant extrahepatic stenosis if it has been stable for 6 months or more (as evidenced on imaging and also clinically), and one of the following are satisfied:
3.1. The principal investigator (PI) does not plan for any biliary intervention (endoscopic, percutaneous or surgical) for the duration of the trial
OR
3.2. The PI decides that they do not wish to perform any biliary intervention (endoscopic, percutaneous or surgical) on the dominant stenosis for clinical reasons of stability/patient choice
4. Presence of a percutaneous drain or bile duct stent
5. Evidence of hepatic decompensation within twelve weeks prior to screening. Hepatic decompensation defined as a variceal haemorrhage, ascites, hepatic hydrothorax, or hepatic encephalopathy
6. Biochemical/laboratory evidence of very advanced hepatic dysfunction, as evidenced by a serum bilirubin value >55 µmol/L (or conjugated hyperbilirubinaemia >45 µmol/L) or Child-

Turcotte-Pugh (CTP) score >B7
7. Ascending cholangitis as assessed clinically within twelve weeks of screening
8. Use of antibiotics within twelve weeks of screening
9. Participant already listed for liver transplantation
10. Small duct PSC
11. Significant renal dysfunction as evidenced by an estimated glomerular filtration rate of <60 ml/min according to the Cockcroft-Gault formula, or need for dialysis
12. Human Immunodeficiency Virus (HIV) infection
13. History of malignancy within the past three years, or ongoing malignancy, other than non-melanomatous skin cancer, or treated cervical carcinoma in situ
14. Any history of small bowel or colonic resection, or likelihood of resection during the trial period.
15. Untreated or poorly controlled IBD, or any IBD that is thought likely to require intensification /changes in treatment during the course of the trial.
16. Patients who are pregnant or breastfeeding
17. Women of childbearing potential (see Appendix 1 for definition) who confirm they are not willing to practise effective contraception (see Appendix 2 for further details) for the duration of the trial and for four weeks after the last dose of trial drug. Women who are taking hormonal contraception must confirm stable formulation and dosage for at least 6 weeks prior to treatment
18. Alcohol consumption >21 units per week for men, and >14 units per week for women
19. Ongoing recreational substance misuse. Those with a prior history must have a negative urine drug screen at screening
20. Positive stool test for Clostridioides difficile toxin or microscopy/culture positivity for enteric infection within twelve weeks prior to screening (note: testing is not mandated during the pre-screening or screening process in the absence of symptoms to suggest an enteric infection).
21. Participation in an interventional trial, or use of a non-licensed investigational agent for any indication within twelve weeks before screening, or five half-lives of the investigational drug, whichever is longer
22. Newly introduced or a change in dosage of any of the following medications within twelve weeks of screening: fibric acid derivatives, farnesoid X-receptor agonists, anti-gastrointestinal motility agents (e.g., loperamide or opioids), bile acid sequestrants (e.g. colestyramine) or ursodeoxycholic acid (UDCA)
23. Use of any of the following medications within twelve weeks of screening: oral or intravenous antibiotics, including (but not limited to) vancomycin, rifaximin, rifampicin and metronidazole; probiotic or prebiotic preparations, including (but not limited to) VSL#3 and Symprove
24. Expected to receive laxatives (including bowel preparation / cleanse for surveillance colonoscopy) during the interventional period of the trial.
25. A symptomatic positive test results for SARS-CoV-2 infection in the four weeks prior to screening. Patients can be re-screened 4 weeks after the positive test result.

Date of first enrolment
13/10/2025

Date of final enrolment
13/08/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
Yaqrit Limited

Funder(s)

Funder type
Research organisation

Funder Name
LifeArc

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	01/10/2025	13/10/2025	No	Yes