

Are you living with Metabolic Associated Steatotic Liver Disease (MASLD)?

Metabolic Associated Steatotic Liver Disease (MASLD), previously known as NAFLD, involves the accumulation of fat in liver cells, often linked to obesity, diabetes, and metabolic syndrome. If left untreated, MASLD can progress to more severe liver conditions. It is estimated that up to one in every three people in the UK has early stages of MASLD.

Why are these trials important?

MASLD is a silent disease that can lead to significant liver damage, including cirrhosis and liver cancer. With limited treatment options currently available, our clinical trials aim to find new and effective therapies that can halt or reverse liver damage in MASLD patients.

About the clinical trials

We are conducting several clinical trials focusing on MASLD, ranging from Phase 1 to Phase 3:

- **Phase 1:** Testing the safety and appropriate dosage of new treatments.
- **Phase 2:** Further assessing the effectiveness of these treatments on a larger group of patients.
- **Phase 3:** Large-scale studies comparing new treatments with current standard treatments to confirm effectiveness.



Current focus:

Our trials are particularly focused on patients with Stage 2 to Stage 4 liver fibrosis (cirrhosis), exploring oral medications and injections that may stop liver fibrosis progression and potentially reverse existing damage.

Key Eligibility Criteria Common to most MASLD trials

To join our trials, you may need to meet the following criteria:

Inclusion criteria

- Male or female patients ≥ 18 years and ≤ 80 years of age at time of consent.
- In Biopsy driven trials require diagnosis of MASH (NAS ≥ 4 , with at least 1 point in inflammation and ballooning each) and fibrosis stage F1–F4.
- BMI ≥ 25 kg/m².

Exclusion Criteria:

- Current or history of significant alcohol consumption.
- Intake of medications historically associated with liver injury.
- Suspicion, diagnosis or history of hepatocellular carcinoma (HCC) or unstable diseases.
- Not on stable dose of diabetes medication (more than 3 months on stable dose sometimes can be included).
- Diagnosis of a serious or unstable disease including hepatic or others.
- HCV cured patients can be enrolled if SVR achieved for more than 1-2 years.
- Few trials also including HBV seroconverted patients with MASLD.

Why participate?

- ▶ **Access to New Treatments:** Be at the forefront of receiving new therapies.
- ▶ **Expert Care:** Receive personalized care from leading specialists in liver diseases.
- ▶ **Contribute to Research:** Help advance medical knowledge and treatment options for MASLD.
- ▶ **Compensation:** You may be eligible for compensation for your time and travel.

How to join?

- **Contact Us:** Reach out to our trials team to express your interest.
- **Initial Screening:** We will schedule a screening to see if you qualify.
- **Participation:** Eligible participants will receive detailed information about the trial and will be closely monitored throughout.

Contact information:

King's College Hospital, Institute of Liver Studies

Senior Research Nurse: Azar Madadi

Specialty Doctor Hepatology: Dr. Saima Ajaz

Tel: 020 3299 4313 **Email:** kch-tr.livertrials@nhs.net

Be part of the future of liver health

Your participation could make a difference in the lives of many living with MASLD.

Should you require more detailed information about the forthcoming studies for MASH, do not hesitate to ask your doctor or nurse to contact the trials team.

PALS

The Patient Advice and Liaison Service (PALS) is a service that offers support, information and assistance to patients, relatives and visitors. They can also provide help and advice if you have a concern or complaint that staff have not been able to resolve for you. They can also pass on praise or thanks to our teams. The PALS office is located on the ground floor of the Hambleden Wing, near the main entrance on Bessemer Road - staff will be happy to direct you.

PALS at King's College Hospital, Denmark Hill, London SE5 9RS

Tel: 020 3299 3601 **Email:** kch-tr.palsdh@nhs.net

If you would like the information in this leaflet in a different language or format, please contact our Communications and Interpreting telephone line on **020 3299 4826** or email kch-tr.accessibility@nhs.net