ISRCTN80904260 https://doi.org/10.1186/ISRCTN80904260

Evaluating new PET imaging tracers to detect active scarring in patients with liver fibrosis and healthy volunteers

Submission date
21/05/2026

Recruitment status
Recruiting

Registration date
07/07/2026

Overall study status
Ongoing

Last Edited
07/07/2026

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Liver fibrosis (scarring) caused by metabolic dysfunction-associated steatotic liver disease (MASLD) is a major health concern. Standard medical scans like ultrasound, CT, or MRI can only show late-stage, permanent structural damage; they cannot measure the active, real-time biological processes or how fast scarring is occurring.
This study is part of the collaborative FIBRE Consortium initiative. It evaluates two novel, non-invasive imaging dyes (radiotracers) called [68Ga]-CBP8 and [18F]-LNTH-1363S, which target specific markers of active tissue remodelling and scarring. The primary aim is to determine if these tracers can successfully map and measure active fibrogenesis in the liver. If validated, they will provide sensitive molecular biomarkers to monitor disease progression and accelerate the early-phase testing of new anti-scarring therapies

Who can participate?
The study will recruit two distinct parallel groups of participants:
Group 1 (Patients): Adults aged 23 to 75 years inclusive with a documented clinical diagnosis of MASLD, advanced liver fibrosis (stages F3–F4), elevated liver fat content (MRI-PDFF > 10%), and specific liver stiffness markers.
Group 2 (Healthy Volunteers): Healthy adults aged 23 to 75 years inclusive with no history of liver disease and normal baseline liver fat and stiffness scores.

All participants must meet protocol-specified weight and BMI ranges (BMI ≥25 kg/m2 for patients; 18.5–24.9 kg/m2 for healthy volunteers), agree to strict contraception guidelines due to low-dose radiation exposure, and consent to identity checks via the Overvolunteering Prevention System (TOPS)

What does the study involve?
Following an initial health screening (that includes MRI scans), participants will attend the imaging centre to undergo advanced Positron Emission Tomography (PET) imaging combined with CT scans.
During these sessions, a small, safe amount of the specialized radiotracers will be administered

via an intravenous injection. The scanners will capture detailed images of active biological activity across the whole liver tissue. To understand exactly how the tracers move, bind, and break down in the body over time, some participants will have temporary arterial lines placed to allow for precise, continuous blood sampling alongside regular vein access.

What are the possible benefits and risks of participating?
Benefits: There are no direct medical or therapeutic benefits to the individual participants in this trial. However, the data will significantly help scientists validate non-invasive imaging tools, ultimately making future clinical trials for liver scarring medications faster, shorter, and more efficient.
Risks: The primary risks involve minor, temporary discomfort, bruising, or swelling at the intravenous injection or arterial blood sampling sites. There is also low-dose radiation exposure from the PET tracers and CT imaging, which is strictly managed and kept well within regulatory and medical safety limits.

Where is the study run from?
The study is sponsored by Perceptive and is conducted at a specialized clinical imaging facility located within the Burlington Danes Building, Imperial College London, Hammersmith Hospital (London, UK). Clinical operations are supported in collaboration with Hammersmith Medicines Research (HMR).

When is the study starting and how long is it expected to run for?
The Phase 1b trial is scheduled to run from July 2026 to July 2028. Individual participant involvement spans from the initial screening assessment through the imaging visits to a final follow-up safety phone call, with the overall study expected to take 24 months to complete.

Who is funding the study?
The study is fully funded and supported by Perceptive as part of the collaborative, pre-competitive investment framework under the FIBRE Consortium initiative alongside its participating partners.

Who is the main contact?
The Chief Investigator is Frans van den Berg, MBChB, at Perceptive (Du Cane Road, London, W12 0NN, UK). Administrative, scientific, and regulatory queries are managed through the Clinical Project Lead at Perceptive using the formal protocol.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
366068

Central Portfolio Management System (CPMS)
70771

Administration of Radioactive Substances Advisory Committee (ARSAC)
AA-13446

Sponsor Code
IMA241619

Study information

Scientific Title
An open-label, multi-tracer, imaging study to evaluate and compare Positron Emission Tomography (PET) tracers targeting Collagen Type I and Fibroblast Activation Protein (FAP) in patients with metabolic dysfunction-associated steatotic liver disease (MASLD) and healthy volunteers

Acronym
The FIBRE study

Study objectives
Study Objectives
1. Primary Objective: To evaluate and compare the liver tissue uptake and distribution of two novel PET radiotracers ([68Ga]-CBP8 and [18F]-LNTH-1363S) in patients with metabolic dysfunction-associated steatotic liver disease (MASLD) versus healthy controls.
2. Secondary Objective: To determine how regional tracer uptake correlates with established clinical markers of MASLD severity and fibrosis stages.
3. Exploratory Objectives: To assess the spatial and quantitative relationship between the two target tracers (Col-1 and FAP) in the patient cohort.
3a. To correlate PET molecular data with structural magnetic resonance imaging (MRI) measurements, specifically liver stiffness (via MRE) and liver fat fraction (via MRI-PDFF).
3b. To cross-reference PET imaging parameters with circulating blood biomarkers of active extracellular matrix (ECM) remodelling.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 16/03/2026, North East - York Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; -; york.rec@hra.nhs.uk), ref: 26/NE/0021

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Diagnostic, Imaging Biomarker Validation / Signal Detection

Study type(s)

Health condition(s) or problem(s) studied
Metabolic dysfunction-associated steatotic liver disease (MASLD), with a specific focus on active liver fibrogenesis (tissue remodelling and the deposition of extracellular matrix/scar tissue

Interventions
This open-label study spans a maximum 8.5-month period per participant, consisting of two screening visits, up to two dynamic PET imaging sessions, and a final follow-up safety phone call 4–7 days post-imaging.
Screening and Baseline: Participants undergo multi-modality liver MRI sequences on a 3 Tesla clinical system during the screening window to establish structural baselines, liver stiffness via Magnetic Resonance Elastography (MRE), and liver fat via proton density fat fraction (MRI-PDFF).
Imaging Sessions: Enrolled participants attend up to two distinct PET imaging sessions separated by a washout period of at least 7 days (and up to 6 months). For logistical convenience, the administration order of the two novel tracers can be interchanged across the sessions. No participant will exceed 2 total PET scans throughout the trial.
Scanner Parameters: All molecular imaging is performed at a single site using a Siemens Biograph Horizon 16 4R PET/CT scanner.
Step-by-Step Scan Interventions
1. Anatomical Localisation: Immediately prior to radiotracer administration, a brief, low-dose CT scan is performed on the participant for anatomical localization and radiation attenuation correction.
2. Tracer Administration: Simultaneously with the initiation of the dynamic PET emission scan, participants receive a single sub-pharmacological intravenous bolus microdose of one of two novel radiotracers:
[68Ga]-CBP8 (targeting collagen type I); mass dose ≤ 100 µg, administered radioactivity ≤150 MBq.
[18F]-LNTH-1363S (targeting fibroblast-activation protein); mass dose ≤ 100 µg, administered radioactivity ≤150 MBq.

3. Kinetic Sampling: To establish a tracer metabolite-corrected plasma input function and quantify parent tracer-related radioactivity over the course of the dynamic scan, intensive vascular blood sampling is performed. This is primarily achieved via a temporary radial artery cannula inserted under local anaesthesia after confirmation of collateral circulation patency via Allen's test. Venous sampling may be utilized as a parallel or alternative method pending emerging data validation. Total blood volume collected for kinetic modelling is strictly capped at 135 mL per tracer injection.
4. Safety Monitoring: Participants are monitored continuously during each PET procedure via pulse oximetry, with pre- and post-scan vital sign evaluations.

Intervention Type
Other

Primary outcome(s)
1. Quantitative liver uptake and tissue distribution parameters of [68Ga]-CBP8 and [18F]-LNTH-1363S measured using regional total volume of distribution, standardized uptake value , and/or SUV ratio derived from whole-organ 3D regions of interest. at a continuous timecourse during each dynamic PET emission scan (at PET imaging sessions 1 and 2, which are separated by a washout period of at least 7 days and up to 6 months)

Key secondary outcome(s)
1. Safety and tolerability parameters of [68Ga]-CBP8 and [18F]-LNTH-1363S measured using the number and severity of adverse events (AEs), serious adverse events (SAEs), and clinically significant changes in vital signs, ECG parameters, and clinical laboratory safety assessments (haematology, biochemistry) at a continuous timeline from the screening visit, pre- and post-injection during PET imaging sessions 1 and 2, and up to the final safety follow-up phone call (4–7 days post-imaging)

2. Correlation between regional PET radiotracer hepatic uptake and established clinical staging of MASLD disease severity, measured using correlation coefficients (e.g., Pearson/Spearman) mapping quantitative tracer tissue distribution metrics (VT, SUV, and SUVR) against non-invasive clinical fibrosis staging scores and liver enzyme profiles (ALT, AST), at a single timepoint cross-referencing screening clinical data with the quantitative PET parameters captured during imaging sessions 1 and 2 (washout window of 7 days to 6 months between scans)

Completion date
01/07/2028

Eligibility

Key inclusion criteria
General Inclusion Criteria (All Participants)
1. Male or female volunteers
2. Agree to follow the contraception requirements of the study
3. Able to give fully informed written consent.

Cohort Specific: Patients with MASLD (Cohort A)
1. Volunteers with a diagnosis of MASLD with F3–F4 liver fibrosis based on historic liver biopsy and non-invasive markers: liver stiffness with magnetic resonance elastography (MRE) ≥ 4.3 kPa
2. Alanine aminotransferase (ALT) > upper limit of normal (ULN) and < 5 × ULN
3. Liver fat content (magnetic resonance imaging-proton density fat fraction [MRI-PDFF]) > 10%

4. Body Mass Index (BMI) ≥ 25 kg/m2
5. registered with a general practitioner (GP) in the UK

Cohort Specific: Healthy Volunteers (Cohort B)
1. Normotensive volunteers deemed healthy on the basis of a clinical history, medical examination, electrocardiogram (ECG), vital signs, and laboratory tests of blood and urine
2. Normal liver stiffness (MRE < 2.5 kPa)
3. BMI in the range 18.5–24.9 kg/m2
4. Liver fat content (MRI-PDFF) < 5%

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
23 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
All volunteers:
1. Positive tests for hepatitis B & C, human immunodeficiency virus (HIV)
2. Severe adverse reaction to any drug
3. History of malignancy or carcinoma in the last 5 years
4. History of liver transplant
5. Presence or history of drug or alcohol abuse
6. Drink more than 14 units of alcohol weekly
7. Smoke more than 10 cigarettes daily or heavy use of e-cigarettes
8. Use of high-dose corticosteroids from 3 months before the first PET scan until the end of the study
9. Participation in other clinical studies of unlicensed medicines, or loss of more than 400 mL of blood, within the 3 months before the first PET scan
10. Clinically relevant abnormal findings at the screening assessment, acute or chronic illness, or clinically relevant abnormal medical history or concurrent medical condition (unless resulting from MASH in Group 1)
11. Possibility that volunteer will not cooperate
12. Pre-menopausal females who are pregnant or lactating, or who are sexually active and not using a reliable method of contraception
13. Unsatisfactory venous access
14. Significant exposure to ionizing radiation (more than 10 mSv) within the previous 12 months

15. Contraindications to arterial cannulation, magnetic resonance imaging (MRI), PET or computed tomography (CT)
16. Objection by General Practitioner (GP).

Date of first enrolment
08/07/2026

Date of final enrolment
01/06/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hammersmith Medicines Research Limited
Cumberland Avenue
London
England
NW10 7EW

Sponsor information

Organisation
Perceptive Discovery

Funder(s)

Funder type

Funder Name
Perceptive Discovery

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available