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Hepatitis C Inoculum Trial (HIT): Blood collection from hepatitis C positive donors for use in a controlled human challenge model

Submission date
17/02/2026

Recruitment status
Not yet recruiting

Registration date
19/02/2026

Overall study status
Ongoing

Last Edited
15/04/2026

Condition category
Infections and Infestations

[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
Hepatitis C Virus currently infects more than 50 million people worldwide and remains a major cause of liver cancer, liver failure and death. This study is the first stage in the development of a human challenge model for hepatitis C Virus infection (HCV), which is needed to test new vaccines that will prevent HCV infection.
The purpose of this study is to collect blood from people living with a hepatitis C virus (HCV) infection from sites in the UK which already provide diagnosis, care, or treatment for HCV infection. The plasma, which contains HCV, will be separated from the collected blood. Scientists will measure the amount of virus in the plasma and store it safely for use in future research studies. In these future studies, healthy volunteers will be intentionally exposed to HCV, and will then be treated and cured of the virus. The goal of this research is to develop better vaccines and possible preventative treatment for hepatitis C.

Who can participate?
People who join this study must have either a long-term (chronic) or recent (acute) HCV infection. First, an individual will go through a health check to make sure they are eligible to take part in the study. This health check includes a medical exam, medical history, and blood and urine tests.

What does the study involve?
After passing the health check, people who enrol in this study (study participants) will donate a moderately large amount of blood (about one unit or 470 millilitres of blood, that is typical of standard blood donation). After this donation, the study participant will receive their usual medical care for HCV through their existing healthcare team. Study participants will attend two further in-person visits (when small volumes of blood will be taken ~4 teaspoons) and one additional remote (telephone call) visit over about a 25 week period following their blood donation. Total enrolment in the study for each participant is expected to be no longer than six months.
Participation is completely voluntary, and study participants can leave the study at any time. By donating, participants may help advance research that could one day prevent hepatitis C

infection and protect millions of people from infection. This study follows safety and ethical rules to protect all participants.

What are the possible benefits and risks of participating?
There are no direct personal benefits to participation. Participants contribute to research that could have significant public health benefits through the development of future prevention tools.
The physical risk to study participants is minimal and limited to standard phlebotomy. The psychological risk is low but possible: i) awareness that one's blood may be used to infect healthy volunteers in future research, ii) learning unexpected findings from infectious disease screening can be distressing.

Where is the study run from?
The study is sponsored by the University of Oxford and primarily run at the Experimental Medicine Research Facility within Oxford University Hospitals NHSFT, with additional sites at 56 Dean Street in Chelsea & Westminster NHSFT and Mortimer Market Centre in Central & NW London NHSFT.

When is the study starting and how long is it expected to run for?
Recruitment is expected to open early 2026 and run until late 2026, with follow up for the final participant/s by mid-2027.

Who is funding the study?
The study is funded by philanthropic donation from Coefficient Giving Action Fund and Founder's Pledge.

Who is the main contact?
Prof. Eleanor Barnes (Chief Investigator)
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
359186

Central Portfolio Management System (CPMS)
69717

Study information

Scientific Title
Hepatitis C chronic and acute donor blood collection for use in controlled human infection model (CHIM)

Acronym
HIT

Study objectives
To develop and characterize both chronic and acute hepatitis C virus (HCV) inocula for use as standardized challenge agents in future controlled human infection model (CHIM) studies.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/01/2026, South Central – Oxford A (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; oxforda.rec@hra.nhs.uk), ref: 25/SC/0383

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)
Other

Health condition(s) or problem(s) studied
Viral hepatitis

Interventions
There is no experimental treatment in this study; standard hepatitis c treatment will be provided by the NHS independently of the study. Participants in the study will be asked only to donate blood samples on 3-4 visits and complete health screening questionnaires. An initial small blood sample (~60mls) is required to screen participants for co-infections before being invited to donate a moderately large volume of blood (~470mls, as a standard donation unit) prior to starting NHS treatment. Thereafter, treatment progress will be assessed by the study team through a remote visit (phone call) and two further small blood samples (~60mls and ~20mls). The last visit may be remote if final treatment results can be provided through the NHS.

Intervention Type
Other

Primary outcome(s)
1. The collection of at least one chronic and one acute donor sample suitable for use in a controlled human infection model (CHIM) measured using review participant case report forms at end-of-study

Key secondary outcome(s))
1. Quantification of HCV viraemia at suitably high levels for use at inoculum measured using blood sample, NHS diagnostic HCV nucleic acid quantification at large donation, day +/-0

2. Successful cure of inoculum donor defined as sustained virological response at week 12 (SVR12) measured using blood sample, NHS diagnostic HCV nucleic acid quantification at last visit, day +175

3. The absence of known HCV resistant associated substitutions (RAS) or additional pathogens measured using blood sample: NHS, UKHSA, commercial, and in-house nucleic acid and serological pathogen tests at screening, day -<30; large donation, day +/-0; follow-up, day +86; final visit, day +175

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study.
2. Aged 18 years or above.
3. Hepatitis C viral load greater than 50,000 IU/ml for participants with chronic hepatitis C; greater than 10,000 IU/ml for participants with acute hepatitis C.

4. Infection with hepatitis C genotypes 1 or 3.
5. Willingness to give blood to be used for the development of an HCV inoculum.
6. Agree to allow study staff to inform and receive information from the participant's clinical care team, including primary and secondary clinical care team, regarding study participation and HCV treatment outcomes.
7. Agree to allow access to clinical records for the duration of the study.
8. Agree to allow access to study records by a study audit team.
9. Eligible and willing to receive currently approved DAA therapy.
10. In the study investigator's and clinical care team's opinions, able and willing to comply with all trial requirements.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Tested positive for HIV.
2. Tested positive for syphilis.
3. Are a hepatitis B carrier (HBcAb and/or HBsAg positive).
4. Are HTLV positive.
5. Cancer diagnosis within the last 12 months or an ongoing cancer diagnosis (except basal cell carcinoma of the skin).
6. Had an organ transplant.
7. Have been diagnosed with variant Creutzfeldt-Jakob Disease (vCJD).
8. Are pregnant or have had a baby in the past 6 months.
9. Have travelled to regions with malaria, dengue, Zika, or other mosquitoborne infections in the last month.
10. Undergoing medical investigation or assessment (e.g., for a heart condition).
11. Haemoglobin levels below at least 130 g/L for men and 115 g/L for women on up to two consecutive visits.
12. History of any serious psychiatric condition in the last 3 years requiring hospital specialist supervision.
13. History of any other serious chronic illness requiring hospital specialist supervision, except active or suspected substance abuse.
14. Populations considered vulnerable under ICHGCP E6(R3) due to potentially compromised ability to give fully informed and voluntary consent, including:
• Individuals who may feel pressured to participate due to professional roles (e.g., medical or

research staff involved in the study).
• Individuals living in institutional or controlled environments (e.g., prisoners).
• Individuals in very unstable social settings (e.g., homeless persons, nomadic populations, certain categories of refugees).
15. Anything else which, in the opinion of the Investigator, may influence the individual's ability to meaningfully consent to or complete the trial.

Date of first enrolment
01/06/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Experimental Medicine Clinical Research Facility (LEAD)
Oxford University Hospitals NHSFT
Churchill Hospital, Old Road
Headington
Oxford
England
OX3 7JU

Study participating centre
56 Dean Street
Chelsea & Westminster NHS FT
Soho
London
England
W1D 6AQ

Study participating centre
Mortimer Market Centre
Central & NW London NHS FT
Capper Street
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WC1E 6JB

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Coefficient Giving Action Fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available