ISRCTN16352397 https://doi.org/10.1186/ISRCTN16352397

LYME-UK – A study of early Lyme disease within GPs in the UK

Submission date
11/08/2025

Recruitment status
Recruiting

Registration date
23/10/2025

Overall study status
Ongoing

Last Edited
17/02/2026

Condition category
Infections and Infestations

[_] 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
Lyme disease is a bacterial infection that occurs in humans through the bite of an infected tick. This is known as a vector-borne disease and Lyme disease is the most common vector-borne disease in the United Kingdom, Europe, and North America. Despite increasing public concern and media attention, there is limited knowledge about how many infections occur, how we accurately diagnose these, and what the long-term outcomes of infections are within the UK. The overall aim is to understand the disease and treatment outcomes over a year, in patients who attend their GP with suspected Lyme disease and are treated with antibiotics.

Who can participate?
Adults aged 18 and over.

What does the study involve?
The study requires 3 clinical visits, to collect blood and urine sample at 3 timepoints, and an optional skin biopsy at baseline. We will also ask symptoms questionnaires over 12 months at 10 timepoints.

What are the possible benefits and risks of participating?
This study will provide data from the tick bite, symptoms, treatment outcomes and serology profile for patients with a diagnosed early infection, within the UK. Participating in the study will enable participants to contribute towards baseline and follow-up data, to help improve understanding of diagnosis and treatment outcomes in patients. Clinical samples will be used in future research to understand Lyme disease infection and to develop improved and new ways to diagnose Lyme disease earlier and more accurately. There is no direct benefit for participants – travel will be reimbursed up to £20 per visit. There is some risk associated with providing a blood sample, with potential discomfort and a small risk of bruising. For participants that provide consent for a skin punch biopsy, there is an additional small risk of infection and discomfort from the procedure. You may also be asked to attend for an extra clinic visit to check healing and removal of a suture if this is used in the procedure.

Where is the study run from?
The study is sponsored by The University of Liverpool. Study and data management is provided by the Global Health Trials Unit, at Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
August 2022 to March 2030

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Professor Neil French, N.French@liverpool.ac.uk
Study coordinator – Ravi Lad, ravi.lad@lstmed.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Neil French

ORCID ID
https://orcid.org/0000-0003-4814-8293

Contact details
University of Liverpool
Liverpool
United Kingdom
L69 3BX
+44 (0)151 795 9630
N.French@liverpool.ac.uk

Type(s)
Public

Contact name
Mrs Rampy Kumar

ORCID ID
https://orcid.org/0009-0007-1775-350X

Contact details
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
L3 5QA
+44 151 705 3755
Lymeuk@liverpool.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
300238

Central Portfolio Management System (CPMS)
60167

Study information

Scientific Title
LYME-UK: A prospective observational cohort study of early Lyme disease within the primary care setting

Acronym
LYME-UK

Study objectives
The study hopes to understand the disease and treatment outcomes over a year, in patients who attend their GP with suspected Lyme disease and are treated with antibiotics as described in the current NICE guidance.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/08/2022, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941106; Wales.REC5@Wales.nhs.uk), ref: 22/WA/0228

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Lyme disease

Interventions
The study will follow patients for up to 12 months without altering their standard treatment. Participants will be recruited from primary care settings when they present with suspected Lyme disease and meet the study's inclusion criteria. They will receive standard antibiotic treatment as determined by their clinicians.

Research samples—including blood and urine—will be collected solely for research purposes and will not influence clinical care. These samples will be processed separately from standard

NHS tests, even if taken during the same venipuncture. Control participants, with no history or symptoms of Lyme disease, will be recruited from the Merseyside region, where Lyme disease incidence is low. They will provide a single set of samples and data at baseline, with no follow-up.

After recruitment, a panel of clinical experts will assess and stratify participants based on diagnostic certainty, using both lab results (e.g., serology, PCR from skin biopsies) and clinical data. All samples will be sent to the Scottish Lyme Disease and Tick-borne Infections Reference Laboratory (SLDTRL) for processing, storage, and analysis. Some anonymized samples will be shared with the Liverpool School of Tropical Medicine for further research. Remaining samples will be stored in a proposed UK Lyme disease repository within the Grampian biorepository facility.

Participants will be given detailed information and can withdraw at any time, with unused samples destroyed upon request. At non-biopsy sites, study procedures include a baseline visit with venipuncture (19.5 ml of blood), a case report form (CRF), and a rash photograph if applicable. Follow-up visits will occur at 3 and 6 months, with similar procedures. Participants will also complete online or paper-based diaries and report forms at baseline, 3, 6, and 12 months. Due to funding constraints, some follow-ups may be limited to 6 months, though efforts will be made to extend this.

At biopsy-capable sites, participants may undergo a minor skin biopsy (2–3 mm) from the rash's edge, following local anaesthetic. This procedure is limited to those who have taken no more than two days of antibiotics to ensure accurate PCR results. All other procedures mirror those at non-biopsy sites.

Control participants will be age and gender matched, recruited from the North West of England, and ideally already scheduled for routine venipuncture. They will attend a single appointment for consent, sample collection, and a brief CRF, with no further follow-up.

Participants will be reimbursed for travel costs. A potential sub-study involving patient-reported outcomes from the UKHSA tick surveillance scheme is mentioned but not yet approved. If viable, it will include participants who report tick bites and Lyme disease, contributing data without clinic visits or sampling. Ethics approval will be sought if this sub-study is pursued.

Intervention Type
Other

Primary outcome(s)
Measured using patient records unless noted:
1. Antibiotic treatment duration and patient compliance over 12 months
2. EM rash resolution with standard treatment over 12 months
3. Longitudinal symptom and severity reporting (Patient Reported Outcome) over 12 months
4. Serology evolution and profile at baseline, 3 and 6 months
5. Microbiological status (skin biopsy subgroup) at diagnosis
6. Patient reported outcomes post-baseline up to 12 months

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/03/2030

Eligibility

Key inclusion criteria
1. GP identified patients who are being treated on clinical suspicion of Lyme disease.
2. Patients 18 years of age or over
3. Availability and willing to attend further appointments for blood/urine samples and complete patient questionnaires.
4. Capacity to provide informed consent to participate in the study
5. Self-caring and mobile

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Contraindication to blood sampling
2. Extreme frailty and/or comorbidity with poor life expectancy
3. Long term antibiotic use

Date of first enrolment
26/07/2023

Date of final enrolment
31/03/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NHS Highland
Reay House
17 Old Edinburgh Road
Inverness
Scotland
IV2 3HG

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200907

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Ravi Lad, ravi.lad@lstmed.ac.uk, anonymous data, after the study close for 15 years, via application and approval from the LYME-UK study team. Any types of analyses. If data are required to be shared, these requests will be documented and saved in the study file, for audit purposes, and all requests will be reviewed and approved by the CI. Data will be transferred through a secure and encrypted portal, to ensure that the file(s) has not been corrupted, maintaining transparency and integrity. All data transfers will abide by the GDPR 2016/679.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Study website	Study website	11/11/2025	11/11/2025	No	Yes