

# A study of arbovirus-infected individuals that have travelled from outside of the UK

<b>Submission date</b> 06/06/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to gather samples and clinical data from individuals who have recently travelled from outside of the UK who have been infected by an arbovirus, including viruses like Japanese encephalitis, dengue, West Nile, yellow fever, and Zika. Arboviruses are transmitted by insects such as mosquitoes, sandflies, midges or ticks which then go on to infect humans. Diagnosis of arboviruses relies on clinical suspicion and slow diagnostic tests. By collecting samples from non-immune individuals with confirmed arbovirus infection, this study will help develop and validate new diagnostic tests.

### Who can participate?

Anyone aged 18 years old and over suspected or confirmed to be infected with an arbovirus by their clinical team

### What does the study involve?

Participants' clinical data will be collected on admission, including blood pressure and tests. Samples will be collected at admission and on days 30 and 180 post-infection. Participants will also complete a quality of life questionnaire at these time points.

### What are the possible benefits and risks of participating?

Participants won't directly benefit, but their involvement will contribute to the development of new arbovirus diagnostics, potentially benefiting future patients. There are minimal risks to participating, as data collection occurs as part of routine clinical practice. The only additional risk is minimal discomfort from venepuncture.

### Where is the study run from?

The University of Liverpool (sponsor) in conjunction with the Global Health Trials unit at the Liverpool School of Tropical Medicine.

### When is the study starting and how long is it expected to run for?

May 2022 to May 2030. The ARBO-UK study will end when either the Health Protection Research Unit (HPRU) funding has been exhausted or the maximum sample size has been reached. Each participant will be followed up for a maximum of 240 days from the presentation.

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

Who is the main contact?  
Dr Lance Turtle (Chief Investigator), [arbo@liverpool.ac.uk](mailto:arbo@liverpool.ac.uk)

## Contact information

**Type(s)**  
Scientific, Principal Investigator

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
306309

**ClinicalTrials.gov number**  
Nil known

## Secondary identifying numbers

UoL001705, IRAS 306309, CPMS 54505

# Study information

## Scientific Title

UK multicentre prospective observational study of imported arboviral infections

## Acronym

ARBO-UK

## Study objectives

This observational study aims to construct a platform to develop arbovirus diagnostics. As a result, there is no primary endpoint specified. The primary objective of this study is to establish a multi-centre initiative to enrol patients diagnosed with arbovirus infections across the UK. Recruitment will be conducted at designated sentinel sites, where clinical admission and follow-up data, along with samples, will be collected from participants. The approach will generate an invaluable resource to support current and future arbovirus diagnostic development.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 16/05/2023, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0) 2071048143; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0008

## Study design

Observational cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital, Laboratory, Medical and other records

## Study type(s)

Diagnostic, Quality of life, Screening

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

## Health condition(s) or problem(s) studied

Humans infected with an arbovirus

## **Interventions**

This observational cohort study aims to recruit 100-200 participants who are followed up for up to 6 months post arboviral infection. Participants will complete a quality-of-life questionnaire (EQ-5D-5L) at admission and on days 30 and 180. Additionally, serum samples, throat swab samples, and human peripheral blood mononuclear cells (PBMC) samples (not collected from all participants) will be collected at these time points. These samples will contribute to the development and testing of new diagnostic assays and assist in further characterizing immune responses, particularly in a non-endemic setting.

## **Intervention Type**

Other

## **Primary outcome measure**

To establish a multi-centre study to recruit up to 200 patients with confirmed arbovirus infections, recruiting from designated sentinel sites to store reference short-term and long-term biological material from across the UK. A participant has been recruited once they have signed an informed consent form, with each participant staying within the study for a maximum of 240 days from presentation.

## **Secondary outcome measures**

1. Collect clinical follow-up data and samples from participants measured using data collected in REDCap, to support the Health Protection Research Unit (HPRU) in Emerging and Zoonotic Infections (EZIs) arbovirus diagnostic development, via percentage CRF completion, at one month and 6 months post-diagnosis
2. Collect peripheral blood mononuclear cells (PBMC) from selected cases in sites with processes in place and the capability to do so, measured using sample collection, to study the natural history of immune responses in well-characterised single virus exposure, aiming to identify optimal epitopes for inclusion in second generation vaccines at Day 0, Day 30 and Day 180
3. To study epitope specificity and how the immune response may change over time from infection to 6 months post-infection

## **Exploratory scientific objectives**

1. To describe the burden of disease and resource utilisation of imported arbovirus infections in the UK, measured using collected medical data of length and type of stay, medication prescribed, and care provided at the end of the study
2. To develop a cohort as a resource for future studies, such as diagnostic studies, or vaccine trials in people with well-defined previous exposure measured using clear documentation and categorization of the exposure history at the end of the study
3. To examine the long-term post-infectious sequelae and effects on people post Arboviral infection, measured using the EQ-5D-5L quality of life questionnaire at Day 0, 30 and 180

## **Overall study start date**

01/05/2022

## **Completion date**

01/05/2030

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 18 years old and above
2. Laboratory confirmed or clinically highly suspected arbovirus infection, defined by: a clinically highly suspected arbovirus is a compatible clinical syndrome in the opinion of the supervising clinician. For example but not exclusively, a patient presenting with a syndrome which may include:
  - 2.1. CNS infection
  - 2.2. Fever and rash
  - 2.3. Fever and myalgia
  - 2.4. Fever and arthralgia
  - 2.5. Plus a negative malaria test
3. Recent travel from another country

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100-200

**Key exclusion criteria**

Clinical syndrome incompatible with the positive diagnostic test

**Date of first enrolment**

20/05/2024

**Date of final enrolment**

01/12/2029

**Locations****Countries of recruitment**

England

United Kingdom

Wales

**Study participating centre**

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital

Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

**Study participating centre**  
**Liverpool University Hospitals NHS Foundation Trust**  
Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**Cardiff and Vale NHS Trust**  
Cardigan House  
University Hospital of Wales  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Sheffield Teaching Hospitals NHS Foundation Trust**  
Northern General Hospital  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**  
**Central Manchester University Hospitals NHS Foundation Trust**  
Trust Headquarters, Cobbett House  
Manchester Royal Infirmary  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2GW

**Study participating centre**

**Royal Free London NHS Foundation Trust**

Royal Free Hospital  
Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**

235 Euston Road  
London  
United Kingdom  
NW1 2BU

**Study participating centre****Barts Health NHS Trust**

The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre****North Bristol NHS Trust**

Southmead Hospital  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre****London North West University Healthcare NHS Trust**

Northwick Park Hospital  
Watford Road  
Harrow  
United Kingdom  
HA1 3UJ

**Study participating centre****Guys And St. Thomas NHS Foundation Trust**

249 Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

## **Sponsor information**

**Organisation**

University of Liverpool

**Sponsor details**

2nd Floor Block D Waterhouse Building, 3 Brownlow Street  
Liverpool  
England



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L69 3GL  
+44 (0)151 794 8739  
sponsor@liverpool.ac.uk

**Sponsor type**  
University/education

**Website**  
<https://www.liverpool.ac.uk/>

**ROR**  
<https://ror.org/04xs57h96>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research Health Protection Research Unit

**Alternative Name(s)**  
NIHR Health Protection Research Unit, Health Protection Research Unit, NIHR HPRU

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
Research institutes and centers

**Location**  
United Kingdom

## **Results and Publications**

**Publication and dissemination plan**  
Planned publication in a peer-reviewed journal

**Intention to publish date**  
01/05/2028

**Individual participant data (IPD) sharing plan**  
The datasets generated during and/or analysed during the current study will be available upon request from Dr Lance Turtle, lturtle@liverpool.ac.uk. The type of data that will be shared

comprises admission clinical data, demographic data, and QoL EQ-5D-5L data at Day 0, 30 and 180. Data will be available within 3 months. Consent from participants was required and obtained. Data is pseudonymised. Any ethical or legal restrictions: Has to be within the UK

### **IPD sharing plan summary**

Available on request