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

Submission date 06/06/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/06/2024	**Overall study status** Ongoing	
Last Edited 01/08/2025	**Condition category** Infections and Infestations	

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

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
306309

Protocol serial number
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

Study type(s)
Diagnostic, Quality of life, Screening

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(s)

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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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
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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

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

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