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Leptospirosis outcomes across a South East Asian cohort

Submission date 09/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/12/2025	**Overall study status** Completed	
Last Edited 10/12/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims

Leptospirosis is the most common bacterial infection that spreads from animals to people worldwide. People can develop a range of symptoms, from none at all, to a mild flu-like illness, to severe disease which can cause inflammation throughout the body, leading to organ damage and death.

Leptospirosis particularly affects people living in low- and middle-income countries, where flooding, poor sanitation, and limited healthcare access make outbreaks more likely. Globally, it is estimated that about 1 million people get leptospirosis each year, and nearly 60,000 die from it. However, these numbers are uncertain because many countries do not regularly collect or report leptospirosis data. This means that there is still the lack a clear picture of how serious the problem is in many parts of the world. This study explores clinical presentations across three countries where leptospirosis is endemic.

- The Philippines, where frequent floods and typhoons, especially in Manila, often lead to outbreaks. In some areas, death rates can be very high — up to 40% during major outbreaks.

- Malaysia, which regularly experiences outbreaks across all states, with the disease becoming more common in recent years.

- Vietnam, where officially lists leptospirosis as a notifiable disease, but many cases are likely missed because the current system relies on clinical diagnosis without laboratory confirmation.

The aim of this study is to bring together data from all three countries to better understand how leptospirosis patients are treated and what outcomes they experience. The researchers aim to identify which factors are linked to severe illness or poor recovery.

Who can participate?

Participants of any age with a clinical or microbiological diagnosis of leptospirosis from a search of hospital records.

What does the study involve?
Data capture was from at least the first health services contact until the end of hospital contact or last study contact. Summary statistics were performed as well as risk analysis of epidemiological or clinical factors associated with primary outcomes.

What are the possible benefits and risks of participating?
The benefit of undertaking this study far outweighs the risks. Undertaking this study, and combining datasets, will lead to a better understand how leptospirosis is treated and which treatments are used in different settings. This study mainly involves reviewing information from medical records or data already available publicly that collected routine clinical data, so the risks are minimal.

Where is the study run from?
The study is jointly run by the London School of Hygiene and Tropical Medicine and Nagasaki University, but the collaborative site where data capture was completed was in Malaysia, Vietnam, and the Philippines.

When is the study starting and how long is it expected to run for?
December 2023 to August 2025.

Who is funding the study?
This research was partially funded by the Nagasaki University WISE Programme.

Who is the main contact?
Dr Nathaniel Lee, nathaniel.lee@doctors.org.uk, nathaniel.lee@lshtm.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Nathaniel Lee

ORCID ID
https://orcid.org/0000-0002-4393-6891

Contact details
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
nathaniel.lee@doctors.org.uk

Additional identifiers

Study information

Scientific Title
The case burden, treatment strategies, and patient outcomes for Leptospirosis across South-East Asia; a multi-country cohort study

Acronym
LEPCO

Study objectives
The primary objective was to explore the major clinical outcomes in the combined cohort to inform the evaluation of a future COS and therapeutic treatment trials.
Secondary objectives included a) summaries of clinical characteristics, treatment regimens, and supportive management; and b) risk analysis of epidemiological or clinical factors potentially associated with clinical outcomes of interest.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 08/01/2016, Research and Ethical Review Board of San Lazaro Hospital (San Lazaro Hospital, Quiricada Street, Manila, 1008, Philippines; +63 2 8732 3777; slh.iso.reru2@gmail.com), ref: Executive approval (electronic copy uploaded)

2. approved 01/12/2019, Institutional Review Board of the Institute of Tropical Medicine (Institute of Tropical Medicine, Nagasaki University, 1-12-4 Sakamoto, Nagasaki, 852-8523, Japan; +8195-819-7803; soumu_nekken@ml.nagasaki-u.ac.jp), ref: 170707170 and 170707170-2

3. approved 01/10/2019, Research and Ethical Review Board of San Lazaro Hospital (San Lazaro Hospital, Quiricada Street, Manila, 1008, Philippines; +63 2 8732 3777; slh.iso.reru2@gmail.com), ref: SLH-RERU-2015-005-E

4. approved 01/10/2019, Institutional Review Board of the Institute of Tropical Medicine (Institute of Tropical Medicine, Nagasaki University, 1-12-4 Sakamoto, Nagasaki, 852-8523, Japan; +8195-819-7803; soumu_nekken@ml.nagasaki-u.ac.jp), ref: 150226136– 4

5. approved 01/06/2012, The Institutional Review Board of Bach Mai Hospital (Bach Mai Hospital, Đ. Gii Phóng/78 Ng. 78 Đ. Gii Phóng, Phương Đình, Đng Đa, Hanoi, 100000, Viet Nam; +84 969 851 616; bnpham2018@gmail.com), ref: 15-IRB, 2011

6. approved 01/06/2012, Institutional Review Board of the Institute of Tropical Medicine (Institute of Tropical Medicine, Nagasaki University, 1-12-4 Sakamoto, Nagasaki, 852-8523, Japan; +8195-819-7803; soumu_nekken@ml.nagasaki-u.ac.jp), ref: 12021085–4

7. approved 14/04/2023, Medical Research Ethics Committee University of Malaya Medical Centre (Jln Profesor Diraja Ungku Aziz, Seksyen 13, Kuala Lumpur, 50603, Malaysia; 03-79493209 /225; ummc-mrec@ummc.edu.my), ref: 2023215-12154

8. approved 26/06/2023, London School of Hygiene and Tropical Medicine Observational /Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +4402076368363; ethics@lshtm.ac.uk), ref: 29255

Study design

Multicentre observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Safety, Screening, Treatment, Other

Health condition(s) or problem(s) studied
Clinical characteristics, treatments, and outcomes of people seen at health institutions with leptospirosis

Interventions
Data capture for all participants was from at least the first health services contact until the end of hospital contact or last study contact. Summary statistics were performed as well as risk analysis of epidemiological or clinical factors associated with primary outcomes.

Intervention Type
Other

Primary outcome(s)
1. All-cause mortality up to the latest follow-up time measured using using data collection from patient medical records at one time point

Key secondary outcome(s))
1. A composite outcome of severe disease including: biochemical evidence of single or multiple organ failure; development of pulmonary haemorrhage; the need for Intensive Treatment Unit (ITU) admission; need for renal replacement therapy (RRT); need for mechanical ventilation; need for oxygen supplementation; and the need for inotropic support or clinical evidence of haemodynamic compromise measured using using data collection from patient medical records at one time point

2. Duration of hospitalization (days) measured using using data collection from patient medical records at one time point

3. Duration of fever (days) measured using using data collection from patient medical records at one time point

4. Hospital discharge measured using using data collection from patient medical records at one time point

Completion date
07/08/2025

Eligibility

Key inclusion criteria
Clinical or microbiological diagnosis of leptospirosis from a search of hospital records

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 years

Upper age limit
87 years

Sex
All

Total final enrolment
3052

Key exclusion criteria
For SLH2 dataset, the following exclusions were applied:
1. Hospitalization last 30 days
2. Fever onset > 48 hours post-hospitalization
3. Blood culture draw ≥ 48 hours after admission
4. Positive microbiological diagnosis of dengue at admission
5. Diagnosis of other viral infection and WBC ≤ 12,000/mm3 or ≥ 4,000 mm3
6. Known underlying chronic disease/condition
7. < 1 year old
8. Declined consent to participate

For BMH1 the following exclusions were applied:
1. Clinical diagnosis of malaria, dengue, food-borne gastroenteritis, cellulitis, or rat-bite fever at admission
2. Microbiological diagnosis at source referral
3. Suspected of having hepatitis-related disease

Date of first enrolment
19/12/2023

Date of final enrolment
07/08/2025

Locations

Countries of recruitment
Malaysia

Philippines

Viet Nam

Study participating centre
University of Malaya Medical Center
Jln Profesor Diraja Ungku Aziz, Seksyen 13
Kuala Lumpur
Malaysia
50603

Study participating centre
San Lazaro Hospital
Quiricada St, Santa Cruz,
Manila
Philippines
1003

Study participating centre
Bach Mai Hospital
Đ. Gii Phóng/78 Ng. 78 Đ. Gii Phóng, Phương Đình, Đng Đa
Hanoi
Viet Nam
100000

Sponsor information

Organisation
Nagasaki University

ROR
https://ror.org/058h74p94

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Not defined

Funder Name
Nagasaki University

Alternative Name(s)
Nagasaki U,

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (LSHTM Data Repository; https://datacompass.lshtm.ac.uk/; or other suitable public repository)

IPD sharing plan summary
Stored in publicly available repository