

Leptospirosis outcomes across a South East Asian cohort

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

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

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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, Phường Đình, Đống 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

Primary study design

Observational

Study design

Multicentre observational longitudinal cohort study

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 $\geq$ 48 hours after admission
4. Positive microbiological diagnosis of dengue at admission
5. Diagnosis of other viral infection and WBC $\leq$ 12,000/mm³ or $\geq$ 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, Phường Đình, Đống 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