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Multicentre case–control study of pneumococcal infections among children with pneumonia in Peninsular Malaysia (MY-Pneumo): a study protocol

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Abstract

Background: *S. pneumoniae* (SPN) is the most common cause of pneumonia. The disease can be effectively prevented through immunisation. Since December 2020, the Malaysian Government has included the 10-valent pneumococcal conjugate vaccine (PCV10) for all infants born on or after 1 January 2020 as part of the National Immunisation Programme (NIP). However, the epidemiology of pneumonia remains poorly understood. To fill the knowledge gap, we established a multicentre surveillance study to understand the burden of pneumococcal pneumonia among young children in Peninsular Malaysia. **Methods:** MY-Pneumo is a multicentre prospective case–control study conducted in three sentinel sites located in three different states of Peninsular Malaysia – Kuala Lumpur, Pahang, and Kelantan. A cohort of at least 500 incident cases and 500 controls is enrolled beginning in October 2021 and matched for age. Cases are hospitalised children < 5 years with radiologically confirmed pneumonia, and the controls are children without any features suggestive of pneumonia. Clinical samples, including nasopharyngeal swabs (NPS) and urine, are collected according to the study protocol. Biological fluids such as blood, cerebrospinal fluid (CSF) and pleural fluid are obtained from invasive pneumonia disease (IPD) patients, if available. All children are tested for SPN using polymerase chain reaction (PCR) and pneumococcal urine antigen test (PUAT) using BinaxNow. **Discussion:** Surveillance data, including carriage rate, serotype variations and the phylogeny data structure of SPN among young children in Malaysia during PCV implementation, will be generated from this study. Trends and patterns of pneumococcal serotypes by different regions are important for targeted public health strategies. Our data will provide baseline information for estimating the impact of PCV10 implementation and will influence policymakers' decisions regarding the upgrade from PCV10 to a higher-valency conjugate vaccine in Malaysia. **Trial registration:** This project was registered at ClinicalTrials.gov (NCT04923035) on 2021, June 11. The study protocol was approved by the International Medical University Joint-Committee on Research & Ethics (4.15/JCM-216/2021) and the Institutional Review Board at sentinel sites (USM/JEPeM/21020190, IREC 2021–114, MREC ID No: 2021128–9769) and University of Southampton's Ethics and Research Governance (ERGo II 64844). © The Author(s) 2024.

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