

PRONTO Trial combines PCT and Clinical Score for Sepsis Management



Euden J, Thomas-Jones E, Aston S, *et al.*PROcalcitonin and NEWS2 evaluation for Timely identification of sepsis and Optimal use of antibiotics in the emergency department (PRONTO): protocol for a multicentre, open-label, randomised controlled trial. *BMJ Open.* 2022;12(6):e063424. doi:10.1136/bmjopen-2022-063424

The Procalcitonin and NEWS2 evaluation for Timely identification of sepsis and Optimal (PRONTO) study is a UK-based multicenter, open-label, randomized controlled trial in adults presenting to the ED.

Currently, clinicians identify and assess sepsis severity using validated clinical scoring systems. In England, the **National Early Warning Score 2 (NEWS2)** is mandated across all National Health Service (NHS) trusts and ambulance organizations and should be used with clinical judgement. However, clinicians often overemphasize the score in patients suspected with an infection, which leads to overprescribing of antibiotics.

Procalcitonin (PCT) is a reliable biomarker that identifies bacterial infections and can be used to support appropriate antibiotic prescribing. However, in the UK, PCT is not routinely used in the care of patients presenting to the emergency department (ED).

The large-scale, multi-center PRONTO (NEWS2 plus PCT) trial is planned to be set in up to 20 NHS EDs in the UK with a target sample size of 7676 participants. The recently released protocol compares standard clinical management based on NEWS2 scoring plus PCT-guided risk assessment with standard clinical management based on NEWS2 scoring alone.

The study will also compare whether this approach reduces antibiotic prescribing without increasing mortality. Thus, a major strength of the PRONTO study is that it addresses coprimary outcomes to assess PCT with NEWS2 evaluation effectiveness as an **antimicrobial stewardship intervention while ensuring safety**.

- Primary objective: assess whether adding PCT measurement to NEWS2 scoring leads to intravenous antibiotic initiation reduction at 3 hours with no increase in a 28-day mortality compared with NEWS2 scoring alone in patients presenting to the ED with suspected sepsis.
 - **Secondary objective:** assess the feasibility, cost-effectiveness, and acceptability to healthcare practitioners, patients, and their family.

Upon completion of the trial, a final report will be prepared for the National Institute of Health Research Health Technology Assessment Journal series and the results will be dispersed locally, nationally, and internationally among scientific, clinical, and lay groups.



"PRONTO is designed to integrate into routine UK clinical pathways and includes assessment of acceptability and practicality in emergency department settings."