New clinical trial underway to improve treatment for newborns with life-threatening sepsis

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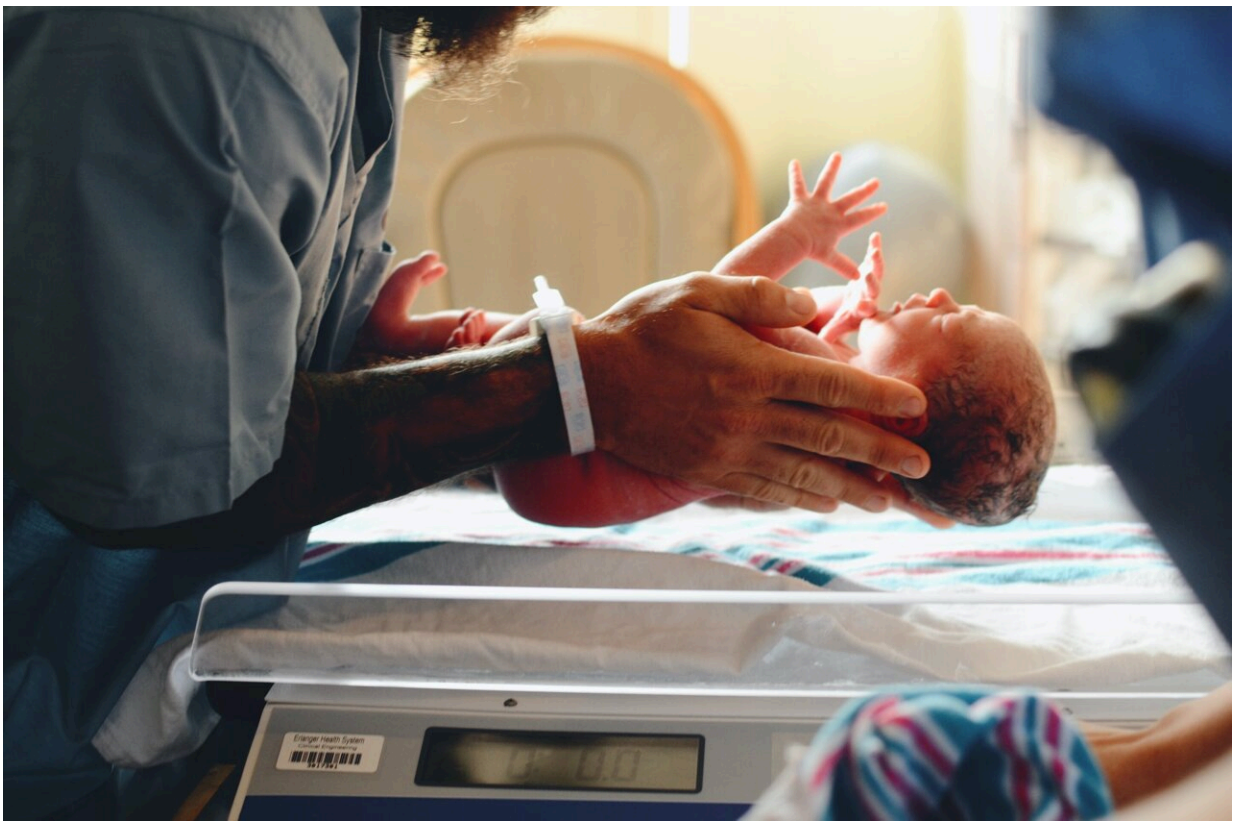

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Researchers at St George's are leading an international clinical trial to evaluate much-needed new antibiotic combinations for newborn babies

with sepsis, thanks to sponsorship from the Global Antibiotic Research and Development Partnership (GARDP).

The trial has now started in three hospitals in South Africa and Kenya and will be expanded to other countries and regions in 2024, with a target of recruiting up to 3,000 newborns overall.

The NeoSep1 trial will evaluate new combinations of existing antibiotics and compare them to treatment regimens that are currently used in newborn babies with suspected neonatal sepsis.

3 million babies affected every year

Neonatal sepsis, a life-threatening infection, affects up to 3 million babies a year globally. This is compounded by the fact that an increasing number of newborns are becoming resistant to WHO-recommended antibiotic treatments, particularly the ampicillin-gentamicin regimen. Over the last decade, antimicrobial resistance (AMR) has worsened to the point that around 50%–70% of common pathogens exhibit a high degree of resistance to available first- and second-line antibiotics. More than 214,000 newborn babies die of drug-resistant neonatal sepsis every year, mostly in low- and middle-income countries (LMICs).

"Newborns handle medicines very differently to older infants, children and adolescents. Premature or otherwise critically ill babies are at great risk of severe infection or sepsis because of their immature immune systems. The types of bacteria causing newborn infections are not necessarily the same as those found in other patients. For these reasons, it is essential to investigate antibiotic treatments of newborns with sepsis," says Dr. Julia Bielicki, pediatrician and researcher at the Center for Neonatal and Pediatric Infection at St George's, University of London.

Seamus O'Brien, director of research and development at GARDP, which is sponsoring the trial, said, "Many babies are dying because of limited treatment options. The NeoSep1 trial is an opportunity to shift this trajectory by identifying new antibiotic combinations that we can tailor to treat neonatal sepsis in settings where there is widespread resistance to current recommended options. This is vital if we are going to address the impact of antimicrobial resistance on the burden of disease related to neonatal sepsis."

The trial will rank the safety and efficacy of three new combinations of older antibiotics (fosfomycin-amikacin, flomoxef-amikacin, and flomoxef-fosfomycin) against the current standard of care. It will also assess and validate the doses of two antibiotics (fosfomycin and flomoxef) for use in newborns.

Varying levels of antibiotic resistance

A key goal is to find out whether some antibiotic treatments perform better than others for the empiric treatment of babies with neonatal sepsis, particularly in LMICs where highly resistant bacteria are common. The trial will also consider how these combination treatments can best be used in hospital settings with varying levels of antibiotic resistance.

A new way of comparing antibiotic treatments with each other, called the Personalized Randomized Controlled Trial (PRACTical) design, will be used. The novelty of this design is that it allows researchers to compare many antibiotic treatments for neonatal sepsis. It will also enable doctors to choose treatment regimens that are likely to work well for newborns in their particular hospital settings.

The NeoSep1 trial builds on findings from a global observational study of sepsis in newborn babies, conducted by GARDP and partners in 19

hospitals across 11 countries from 2018 to 2020. GARDP published a report on the study in 2022.

The study found a worryingly wide variation in treatment and frequent switching of antibiotics because of high resistance to treatments.

Supporting doctors with treatment decisions

The trial now aims to generate relevant and reliable evidence for doctors who need to make treatment decisions.

Expanding the number of suitable, effective treatment regimens could be lifesaving for newborns and could also decrease the risks of neuro-developmental impairment.

Provided by St. George's University of London

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