

Costly treatment 'ineffective for babies'

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(Medical Xpress) -- A worldwide study involving University of Sydney researchers has concluded that a costly and controversial treatment for neonatal sepsis is ineffective.

Neonatal sepsis - a leading cause of infant death - is a [blood infection](#) in newborn babies.

The International Neonatal Immunotherapy Study (INIS), investigated the use of intravenous immune globulin (IVIG) as a treatment for infection in more than 3000 babies from [neonatal intensive care](#) units across the globe.

The study, published today in the [New England Journal of Medicine](#), concluded that the rate of death or severe disability in babies with suspected or proven neonatal sepsis who were given IVIG was the same - 39 percent - as in those who were given the placebo.

Professor William Tarnow-Mordi, Director of Neonatal Trials at NHMRC Clinical Trials Centre, University of Sydney, and Director of the WINNER Centre for Newborn Research, said newborns have low levels of antibodies against infection, known as immune globulins. Earlier research had suggested that treatment with IVIG, a human blood product extracted from donated blood, could reduce deaths in babies with serious infection by half.

Professor Tarnow-Mordi, who led the study in Australia said: "While some authorities had recommended routine IVIG in babies with

suspected infection, others have been waiting for the results of INIS.

“IVIG is not cheap and supplies are strictly limited. It requires significant time and effort to administer, with added risks of fluid overload or of introducing hospital-acquired infection.

“This study rules out, beyond reasonable doubt, the moderate reductions in death or disability which we were looking for. Reducing the use of IVIG in [babies](#) could help free up this precious resource for other sick patients.”

Associate Professor John Ziegler, Chair of NSW Health IVIG Users Group, said: "Members of the INIS Collaborative Group are to be congratulated on a major achievement. This encourages others to investigate, with equal rigour, whether IVIG is effective - and cost effective - in other illnesses where a role for IVIG is suspected but not established."

Professor Warwick Anderson, Chief Executive Officer of the National Health and Medical Research Council, added: “The International Neonatal Immunotherapy Study illustrates the importance of reliable, high quality research for clinical policy across all age groups.”

More than 40 percent of the newborns participating in the trial were recruited in neonatal units in Australia or New Zealand, coordinated through the National Health and Medical Research Council Clinical Trials Centre at the University of Sydney.

Worldwide, the trial was co-ordinated by the National Perinatal Epidemiology Unit in the University of Oxford, led by Professor Peter Brocklehurst.

Provided by University of Sydney

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