The Ottawa Hospital | L'Hôpital d'Ottawa

Research project summary

Cellular Immunotherapy for Septic Shock (CISS): A Phase II Trial

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- Co-Investigators: Duncan Stewart, Shirley Mei, David Courtman, Claudia Dos Santos, Shane English, Alison Fox-Robichaud, John Granton, Robert Green, Paul Hébert, Margaret Herridge, John Marshall, Sangeeta Mehta, Timothy Ramsay, Kednapa Thavorn, Alexis Turgeon, Keith Walley, Brent Winston
- Awarded $100,000 from the Canadian Institutes of Health Research (CIHR) in May 2017

Severe infection with shock (septic shock) in the intensive care unit (ICU) is common accounting for approximately 20% of admissions, of which 30-40% will die. Septic shock is associated with an immensely uncontrolled inflammatory response from the body that is initiated by the infectious organism. Recent studies done in animals with sepsis suggest that the infusion of stem cells balance inflammation, help repair injured organs, clear bacteria and reduce death. Hence, it represents an exciting and promising potential therapy for septic shock. Our team recently completed the first in the World Phase I dose evaluation and safety trial of stem cells (n=9) versus controls (n=21) in 30 patients with septic shock (Cellular Immunotherapy for Septic Shock (CISS Phase I trial)). The CISS Phase I trial results confirmed the optimum dose and that treatment with stem cells is safe. The CISS Phase II trial (CISS2) will continue to evaluate safety and determine whether these stem cells improve clinical and patient important outcomes. CISS2 will randomize 114 patients who are admitted to the ICU with septic shock to 300x106 previously frozen stem cells or placebo across 10 Canadian centres over 2.5 years. The frequency of adverse events and serious adverse events will be recorded. CISS2 will also determine whether stem cells as compared to placebo reduce organ failures. Blood will be drawn repeatedly over time for inflammation markers and the effectiveness of this therapy as compared to its cost will be evaluated after the CISS2 trial is completed. Careful monitoring by an independent and expert committee will review the occurrence of adverse events during the trial. Information gained from CISS2 will be used to secure industrial partnerships to support a definitive international multi-centre Phase III stem cell therapy trial which if positive could result in saving thousands of lives and restoring the function and quality of life of survivors of this devastating illness.

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