

S.A.F.E. Study confirms ALBUMEX can be used safely* in fluid resuscitation

CSL Limited today announced that the S.A.F.E. (Saline versus Albumin Fluid Evaluation) Study, published in the prestigious New England Journal of Medicine, proves conclusively that ALBUMEX (Human Albumin) can be used safely for the fluid resuscitation of patients in intensive care¹.

Chair of the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group, and lead investigator of the S.A.F.E. Study, Dr Simon Finfer, said, "The data clearly demonstrate that in a heterogeneous population of intensive care unit patients, fluid resuscitation with either albumin or saline results in equivalent 28-day all cause mortality."

Dr Finfer added that the S.A.F.E. Study findings "do not support the results of the Cochrane Injuries Group Albumin Reviewers' meta-analysis which suggested the use of albumin resulted in increased mortality in critically ill patients². Clinicians can now be confident that in a heterogeneous population of intensive care patients, albumin and saline are equally safe."

"This data puts to rest any conjecture regarding the overall safety of ALBUMEX in the treatment of these patients in intensive care, and justifies CSL's strong commitment to the manufacture of safe and effective plasma products such as ALBUMEX" said Dr Darryl Maher, Medical and Research Director, CSL Bioplasma.

Within this heterogeneous population the response of several predefined subgroups to fluid resuscitation with either albumin or saline was investigated. The researchers are now doing further analysis to determine which of those subgroups should be investigated in more detail. This will shed light on the possible subgroup differences suggested by the initial data set.

Dr Darryl Maher said "The S.A.F.E. Study, which has been internationally recognised for its large patient sample size and excellent design, confirms what many clinicians already thought, that ALBUMEX can be used safely for a heterogeneous population of critically ill patients requiring fluid resuscitation."

The 7,000 patient S.A.F.E. Study is the single largest clinical trial ever conducted in the intensive care setting. Conducted in 16 centres in Australia and New Zealand, the S.A.F.E. Study was supported and funded by the Australian and New Zealand governments, the Australian National Health and Medical Research Council, the New Zealand Health Research Council, the Australian and New Zealand Intensive Care Society (ANZICS) Clinical Trials Group, the Australian Red Cross Blood Service, The George Institute for International Health and CSL Limited (via an unconditional research grant).

CSL Bioplasma, a division of CSL Limited, is Australia's national fractionator. ALBUMEX is fractionated from blood and plasma voluntarily donated by Australians. These donations are collected by the Australian Red Cross Blood Service.

In addition to the provision of the products used in the S.A.F.E. Study, CSL Bioplasma designed and provided the novel blinding system used to package the albumin and saline administered in this double blinded randomised controlled study.

ALBUMEX is available in two concentrations, ALBUMEX 4 (4% Human Albumin) and ALBUMEX 20 (20% Human Albumin). ALBUMEX 4 is approved for fluid resuscitation (ie. the treatment of hypovolaemia/shock), and for cardiopulmonary bypass surgery and plasma exchange. ALBUMEX 20 is approved for the treatment of hypoproteinaemia in the acutely ill patient, shock, burns, adult respiratory distress syndrome, haemodialysis and therapeutic plasma exchange.

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* use of either 4% albumin or of normal saline results in equivalent 28-day all cause mortality

Dr Simon Finfer is the Senior Staff Specialist in Intensive Care at Sydney's Royal North Shore Hospital

Note:

Unwanted effects associated with albumin administration include allergic type reactions, low blood pressure, shivering and coldness, fever or nausea and vomiting and laboratory abnormalities. For further information, including Boxed Warning, refer to the Consumer Medicine Information for ALBUMEX which is available on CSL Limited's website (<http://www.csl.com.au>).

References

1. N Engl J Med 2004; 350:2247-2256
2. BMJ 1998; 317:235-240



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