Study shows that blood poisoning drug withdrawn by manufacturer may be effective after all

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A controversial drug used to treat patients with severe sepsis (a whole-body inflammatory response often bought on by blood poisoning) withdrawn by manufacturer Eli Lilly in October 2011 due to concerns over its efficacy may offer some benefit to patients after all, according to a new systematic review of the evidence published in the Lancet Infectious Diseases.

The drug, called drotrecogin alfa (activated) and marketed by manufacturer Eli Lilly as Xigris, was approved for use in the United States in 2001, and in Europe in 2002, on the basis of the randomised, double-blind, placebo-controlled PROWESS study.

However, concerns were raised over the drug's efficacy and side-effects, and a second clinical study (PROWESS-SHOCK) led to Eli Lilly withdrawing the drug in October 2011, with the US FDA (Food and Drug Administration) making a Safety Announcement in which it stated that drotrecogin alfa (activated) treatment should be stopped in patients being treated with the drug, and no new patients should be prescribed the drug.

The Lancet Infectious Diseases Article published today [Monday, July 16] examines real-life usage of the drug over a period of ten years, and concludes that the efficacy of Xigris is, in fact, comparable to that suggested by the original PROWESS trial. Use of the drug was

associated with an 18% reduction in the relative risk of death in hospital for patients with severe sepsis, and the authors found no significant differences between the mortality reductions reported by industry-sponsored and independent controlled studies.

According to the study's authors, Dr Andre Kalil of the University of Nebraska Medical Center, USA, and Dr Steven LaRosa of Beverly Hospital, USA, "Compared with the PROWESS trial, real-life use of drotrecogin alfa (activated) was associated with…a similar and significant reduction in the risk of death…Our effectiveness findings accord with PROWESS but not with the PROWESS-SHOCK trial."

Dr Jean-Louis Vincent of the Free University of Brussels, the author of a linked Comment published alongside the Article, said: "Although these data might not represent the highest levels of evidence, many of us (including me) maintain that we can learn a lot from such real-life studies. The death rate from sepsis is unacceptable and new drugs are needed urgently, so one might ask whether drotrecogin alfa (activated) can be resurrected. However, unfortunately Eli Lilly has given up and the drug cannot be produced easily."*

More information:
Abstract
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