

Drotrecogin Alfa (Activated) in Adults with Septic Shock

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ABSTRACT

BACKGROUND

There have been conflicting reports on the efficacy of recombinant human activated protein C, or drotrecogin alfa (activated) (DrotAA), for the treatment of patients with septic shock.

METHODS

In this randomized, double-blind, placebo-controlled, multicenter trial, we assigned 1697 patients with infection, systemic inflammation, and shock who were receiving fluids and vasopressors above a threshold dose for 4 hours to receive either DrotAA (at a dose of 24 μ g per kilogram of body weight per hour) or placebo for 96 hours. The primary outcome was death from any cause 28 days after randomization.

RESULTS

At 28 days, 223 of 846 patients (26.4%) in the DrotAA group and 202 of 834 (24.2%) in the placebo group had died (relative risk in the DrotAA group, 1.09; 95% confidence interval [CI], 0.92 to 1.28; $P=0.31$). At 90 days, 287 of 842 patients (34.1%) in the DrotAA group and 269 of 822 (32.7%) in the placebo group had died (relative risk, 1.04; 95% CI, 0.90 to 1.19; $P=0.56$). Among patients with severe protein C deficiency at baseline, 98 of 342 (28.7%) in the DrotAA group had died at 28 days, as compared with 102 of 331 (30.8%) in the placebo group (risk ratio, 0.93; 95% CI, 0.74 to 1.17; $P=0.54$). Similarly, rates of death at 28 and 90 days were not significantly different in other predefined subgroups, including patients at increased risk for death. Serious bleeding during the treatment period occurred in 10 patients in the DrotAA group and 8 in the placebo group ($P=0.81$).

CONCLUSIONS

DrotAA did not significantly reduce mortality at 28 or 90 days, as compared with placebo, in patients with septic shock. (Funded by Eli Lilly; PROWESS-SHOCK ClinicalTrials.gov number, NCT00604214.)

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*Investigators in the Prospective Recombinant Human Activated Protein C Worldwide Evaluation in Severe Sepsis and Septic Shock (PROWESS-SHOCK) study group are listed in the Supplementary Appendix, available at NEJM.org.

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Table of Contents New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1

1. Understanding the eBook New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - The Rise of Digital Reading New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Advantages of eBooks Over Traditional Books
2. Identifying New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms

- Features to Look for in an New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
- User-Friendly Interface
- 4. Exploring eBook Recommendations from New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Personalized Recommendations
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 User Reviews and Ratings
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 and Bestseller Lists
- 5. Accessing New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 Free and Paid eBooks
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 Public Domain eBooks
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 eBook Subscription Services
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 Budget-Friendly Options
- 6. Navigating New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 eBook Formats
 - ePub, PDF, MOBI, and More
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 Compatibility with Devices
 - New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1 Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Highlighting and Note-Taking New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Interactive Elements New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
- 8. Staying Engaged with New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Joining Online Reading Communities

- Participating in Virtual Book Clubs
- Following Authors and Publishers New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
- 9. Balancing eBooks and Physical Books New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Setting Reading Goals New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Fact-Checking eBook Content of New England Journal Of Public Policy Special Issue On Aids Winter Spring 1988 Vol 4 No1
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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