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1. The manuscript is not simultaneously being considered by other journals.
2. The manuscript has no redundant publication, plagiarism, data fabrication or falsification.
3. Conflicts of interest are disclosed in the manuscript.
Authors Hernández-Bernal F, Valenzuela-Silva CM, Aguilera-Barreto A, and López-Saura PA, are employees of the Center for Genetic Engineering and Biotechnology, Havana Network, where rSK is produced and the new formulation was developed. Catasús-Álvarez KM is also from this Center at present but not when the trial was done. Aguilera-Barreto A is author of the rSK product patent (WO2004058219 A1; Formulations for the rectal administration of thrombolytically-active agents). The remaining authors have no conflict of interests. No honoraria, consulting fees or payments for seminar presentations, speeches or appearances have been received by any of the authors.
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