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Drotrecogin alfa (activated) in severe sepsis

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To overcome the difficulties of non-randomised comparisons in the recent meta-analysis1 of drotrecogin-alfa (activated), investigators extracted and pooled both adjusted and raw outcome estimates from nine observational controlled studies (references 21–28 in Kalil and LaRosa). The meta-analysis included our 2007 GiViTI study (reference 21 in Kalil and LaRosa), which showed a significant 15% reduction in risk ratio that was was pooled with the other adjusted analyses. However, this risk ratio was calculated on the basis of raw mortalities, and was therefore not an adjusted value. By contrast, in our GiViTI study the drug seemed to harm elective surgical patients (OR 2· 79, 95% CI 1· 31–5· 97) after adjustment for relevant confounders; therefore, our data were improperly used to support the efficacy of drotrecogin alfa (activated). Moreover, the sensitivity analysis focused on non-randomised controlled studies, aimed to assess the potential bias caused by conflict of interest, included only sponsored studies, and not all the studies for which a conflict of interest was declared (six of the nine studies).