British soldiers are “guinea pigs” for new use of blood clotting agent

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British soldiers in Iraq are being treated for traumatic injury with an unlicensed blood clotting agent that has yet to complete clinical trials.

The drug, NovoSeven, also called recombinant factor VIIa, has been licensed for the treatment of haemophilia since 1999 but is still undergoing phase III trials as treatment for traumatic bleeding. It was first used in a military setting four years ago, on a wounded Israeli soldier, and has since been used by US forces in Iraq.

A spokesman for the Ministry of Defence said, “The use of recombinant factor VIIa has been authorised only after a very extensive review of the current evidence. This is a proven, lifesaving treatment. It has only twice been administered—in the two separate incidents in Iraq, and on both occasions the individuals’ lives were almost certainly saved by the treatment. It is used only in extremis, when the casualty has suffered a catastrophic trauma, and when no other treatments are viable or available. The NHS also recognises the benefits of this treatment in similar circumstances and has advised us that UK hospitals have also used the drug to treat severe trauma patients.”

But Professor Ian Roberts, an epidemiologist at the London School of Hygiene and Tropical Medicine, said that anecdotal evidence of success could be highly misleading. “Things get into medicine by the back door this way. Anecdotes about success pile up, and, before you know it, it’s the standard treatment, but it’s still not proven. You only have to look at albumin in resuscitation or steroids in head injury to see that.”

Professor Roberts led the CRASH (corticosteroid randomisation after significant head injury) trial, which found that steroid use in traumatic head injury, although widely accepted for years as standard treatment, actually increased mortality and had caused thousands of deaths. “All drugs have the potential to harm and clotting agents more than most,” he said.

The Liberal Democrat science spokesman Evan Harris, a former hospital trauma specialist, said, “I think it’s reasonable for the Ministry of Defence to provide this treatment outside the current licence—in extremis—while phase III trials are under way, as long as they publish their dossier of anecdotal evidence, in the interests of transparency. They should also undertake to publish case studies of soldiers treated, to contribute to the body of knowledge.”

Shaun Rusling, of the National Gulf War Veterans and Families Association, said that he feared that soldiers were being used as guinea pigs because they had less power to withhold
informed consent, especially when severely wounded. “It’s very reminiscent of 1991, and the unproven vaccines we were given then,” he said.

“Knowing the Ministry of Defence as I do today,” he added, “I worry what will happen if, for example, these guys develop heart problems 10 years down the road. The ministry will say, ‘Not me; don’t know what you’re talking about; I lost the paperwork.’”