

The Department of Defense is investigating whether 80 wounded American service members in Iraq were improperly used as subjects in a test of a possible treatment for brain injuries, according to the Pentagon's Office of Inspector General.

The study, sponsored by the United States Naval Medical Center in San Diego, was designed to test whether a drug made to treat Tylenol overdoses, among other uses, could also reduce the harmful effects of traumatic brain injury, such as balance loss and brain function problems, in service members who had been hit by explosions.

The investigation, triggered by an allegation made last year to a Department of Defense hotline, is reviewing the study for possible research misconduct on human subjects. The Pentagon has not said whether anyone was hurt as a result of the administration of the drug.

In addition to the defense investigation, the US Navy is conducting an inquiry into alleged research misconduct and potential violations of the Uniform Code of Military Justice, according to Jennifer Plozai, a spokeswoman for the Pentagon's inspector general, in response to questions from the Globe. She declined to spell out the nature of the alleged misconduct.

Medical tests on human subjects must follow strict rules in their design and execution to protect the safety of patients, said Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania. Test subjects must be competent and able to understand the test and its implications, participation must be voluntary without any pressure, and all test subjects must be fully informed of the potential risks before they consent to take part, he said.

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