ICU
MANAGEMENT & PRACTICE

CHEST Trial - BMJ Stirs Controversy Over Data Release

Use of starch for fluid resuscitation was suspended by European and U.S. regulators following publication in the *New England Journal of Medicine* of the results of the CHEST trial (Myburgh et al. 2012), which raised safety concerns.

Fresenius Kabi, which makes hydroxyethyl starch (HES) products and was a sponsor of the CHEST trial, has claimed that they have discovered problems in the CHEST investigators' handling of adverse event data. However, the company has been refused access to the trial's data. The controversy is described in an editorial in the *BMJ*. The *BMJ*'s Associate Editor Peter Doshi, who is Assistant Professor, University of Maryland School of Pharmacy, Baltimore, USA, asks, is it right for academics to withhold data and prevent independent scrutiny of their results? Doshi points out that when regulators issued public warnings about HES products, they did so without any access to the CHEST trial's underlying data. He says this case "It's an important case because it flips the usual narrative of industry refusing to share data with academics.. it highlights the degree to which current scientific publishing practices and regulatory decisions are based on blind trust and strengthens the call for a shift to open data."

The publishing journal, *NEJM*, told the company that there had been no breach of scientific protocol and that no change was needed to its published material. The trial investigators have refused to share the raw study data because they are concerned that the company would bias the reanalysis. They have also refused a request to release the data to Yale cardiologist Harlan Krumholz for reanalysis by independent parties under his Yale open data access (YODA) scheme.

See Also: Transparency Matters: New EMA Agreement

Principal CHEST trial investigator, John Myburgh said "We have no issue with the concept of data sharing. The concerns we have come down to the people with ulterior motives which contradict or do not adhere to the scientific principles we adhere to. That's the danger." Myburgh is confident about the conclusions that can be drawn from his trial. The BMJ quotes anonymously another CHEST study investigator who was not a coauthor of the NEJM article who says that he was "uncomfortable with the way renal complications were interpreted [in the NEJM paper]. We found two opposite effects: more use of renal replacement therapy in the HES group but more renal risk and injury according to the RIFLE criteria in the saline group."

Doctor "and transparency advocate Ben Goldacre, who advised Fresenius Kabi, said "The researchers should hand these data over, and if they want to be taken seriously, the sponsors [Fresenius Kabi] should set out their protocol for analysing it before they receive the files."

Source: BMJ
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