**Fraudulent GSK trial of steroid for smoker’s lungs and Cochrane fraud, too**

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24 April 2025

This little article is a copy of a section in my autobiography, *Whistleblower in healthcare*, which can be downloaded for free here: <https://www.scientificfreedom.dk/books/>. It described how both GSK, AstraZeneca and Cochrane committed fraud, to the benefit of steroid, which didn’t work and was actually harmful.

Smoker’s lungs, or chronic obstructive pulmonary disease (COPD), is a gigantic market, about 400 million people.[[1]](#endnote-1) In 2007, GlaxoSmithKline (GSK) published a huge trial in the *New England Journal of Medicine* aimed at finding out if it was beneficial to give corticosteroid inhalations to these patients.[[2]](#endnote-2) The trial’s name, TORCH, was suspicious: *Towards a Revolution in COPD Health*. How could GSK know this before they had done the trial?

The primary outcome was death. GSK randomised 6184 patients to four groups:placebo; salmeterol (a long-acting asthma drug); fluticasone (a steroid); and both drugs together. This factorial design is powerful. It allows the investigators to study three research questions instead of one, without increasing the same sample size. Such a trial can tell us if the two drugs are effective, and if the combination is better than any of its components.

But nowhere in the 15-page trial report was the correct factorial analysis to be found, and the abstract gives the readers the impression that the combination is better than any of its components: The combination had reduced deaths by 17.5% (P = 0.052 compared to placebo) whereas “the mortality rate for salmeterol alone or fluticasone propionate alone did not differ significantly from that for placebo.” This was fraud. GSK did not provide the correct analysis in the main text of the paper either.

The authors of a letter to the editor reported the correct factorial analysis.[[3]](#endnote-3) The effect of the combination was entirely due to salmeterol and this effect, a 19% reduction in deaths, was significant (P = 0.004). Fluticasone did not work at all (P = 1.00). Another letter pointed out that pneumonia occurred more frequently when people received fluticasone (in 19% of the patients) than in the placebo or the salmeterol only groups (13%).[[4]](#endnote-4) The number needed to harm was only 17 (P < 0.001).

In their reply, the TORCH trial authors, which included an employee of GSK, committed more fraud. They said a factorial analysis assumes that each treatment has the same addi-tive effect in the absence and presence of the other treatment and that this was not the case.[[5]](#endnote-5) They didn’t verify their claim, and it was wrong. Other researchers documented eight months later that a factorial analysis was indeed appropriate, as the interaction term was not statistically significant (P = 0.32).[[6]](#endnote-6) They published this in another journal. I assume the editors of *New England Journal of Medicine* rejected their letter because it showed that the trial authors lied, which would reflect badly on the editors - who were complicit in the fraud, as they had published something that was so utterly and obviously misleading.

The trial authors claimed that the combination was superior, with fewer exacerbations and better health status, but this was also misleading. It was not superior for the primary outcome, death, and as it caused more pneumonias, it was clearly inferior. In addition, the secondary outcomes were not reliable because many patients discontinued treatment, and the analyses only included data up to that point, which is bad science.

What made me study this trial in detail was that GSK in 2013 published a full-page ad in a Danish industry-funded magazine that claimed that the combination (Seretide, called Advair in the UK), reduces the decline in lung function in patients with chronic bronchitis and would give them a better life.[[7]](#endnote-7) This was also fraud. The source of the lung function data was a post-hoc analysis of 86% of the patients in the TORCH trial.[[8]](#endnote-8) This analysis showed - once again - that the combination was not better than any of its components. A tiny difference of 3 mL (healthy people lose 30 mL per year) between the combination and each treatment alone was not statistically significant (P = 0.44 and 0.45, respectively). But the ad didn’t men-tion these results. It said that the difference between the combination and placebo was statistically significant (P < 0.05).

The post-hoc paper had ten authors. Three were GSK employees, and the other sevenwere on GSK payroll, e.g. as advisory board members, speakers, and consultants. Two additional people, one from GSK and a ghost writer (euphemistically called a professional medical writer), were not listed as authors but were acknowledged for “technical support.”

When I drew attention to the misleading marketing and research in our medical jour-nal,[[9]](#endnote-9) GSK did not address any of my criticisms but stated that they were confident that the Danish authorities and specialists were fully capable of making decisions and guidelines that benefit the patients.[[10]](#endnote-10) They called their bullshit reply, *Openness and dialogue is the answer*. GSK had been anything but open, did not enter a dialogue with me or others, and committed fraud repeatedly to lure the doctors into using a drug that was double as expensive than the drug that worked, salmeterol.

One of the trial authors on industry payroll, Jørgen Vestbo, was aggressive and menda-cious. Under the false headline, *The claims by Peter Gøtzsche about scientific article are untrue*, he argued that one should not do analyses that were not prespecified in the trial protocol,[[11]](#endnote-11) which was also false. The published protocol stated: “The other objectives of the study include comparisons of mortality in the SFC [combination] group with that seen in the salmeterol and FP [steroid] groups, and in the salmeterol and FP groups compared with the placebo group.”[[12]](#endnote-12)

In other such trials, both GSK and AstraZeneca failed to do the appropriate analyses,[[13]](#endnote-13) which means that the whole research area is a fraud. The crimes paid off handsomely. In 2012, the sales of the combination were four times larger than the combined sales of the two components.[[14]](#endnote-14)

The Cochrane Airways Group also contributed to the fraud by committing editorial miscon-duct. I submitted my criticism of the TORCH trial three times to the editors, but they refused to change the Cochrane review that was similarly misleading as the TORCH trial, which I explained in my published criticism of the review.[[15]](#endnote-15) The editors tried to dismiss my valid criticism by quoting the authors of the TORCH trial who claimed that a factorial analysis would not be appropriate. Oddly, they quoted the paper whose authors demonstrated that a factorial analysis was indeed appropriate, without mentioning this crucially important finding. I noted that I had downloaded the clinical study report for the TORCH trial from GlaxoSmithKline’s website (5,481 pages), from which it is clear that GSK should have done a factorial analysis, also because the trial was clearly factorial in its design.

I complained to Cochrane’s Editor-in-Chief to no avail, even though the Cochrane review is fraudulent. The authors implied that the combination drug lowers mortality even though the steroid had no role in this.

Cochrane is too close to the drug industry and has not even acknowledged that industry funding of trials is an important biasing factor. In 2013, Cochrane statistician Jonathan Sterne argued why the funding source should not be part of Cochrane’s risk of bias tool. Sterne was out of touch with reality and the research in this area, which I noted.[[16]](#endnote-16) He showed his true face when he wrote: "Adding source of funding as a bias domain in the risk of bias tool would send an extremely negative message to pharmaceutical industry colleagues with whom we should be happy to work, and it might have the unintended consequence of labelling high-quality trials as biased."

It has been shown abundantly that many industry-sponsored “high-quality trials” are fraudulent. And why would we be happy to work with people in an industry that doesn't allow access to the data, not even for the doctors in hospitals that collected them?

1. [Smoking is the leading cause of chronic obstructive pulmonary disease](https://www.who.int/news/item/15-11-2023-smoking-is-the-leading-cause-of-chronic-obstructive-pulmonary-disease). WHO 2023;Nov 15. [↑](#endnote-ref-1)
2. Calverley PM, Anderson JA, Celli B, et al. Salmeterol and fluticasone propionate and survival in chronic obstructive pulmonary disease. N Engl J Med 2007;356:775-89. [↑](#endnote-ref-2)
3. La Vecchia C, Fabbri LM. Prevention of death in COPD. N Engl J Med 2007;356:2211-2. [↑](#endnote-ref-3)
4. Duerden M. Prevention of death in COPD. N Engl J Med 2007;356:2212. [↑](#endnote-ref-4)
5. Calverley P, Anderson J, Celli B. Prevention of death in COPD. N Engl J Med 2007;356:2213–4. [↑](#endnote-ref-5)
6. Suissa S, Ernst P, Vandemheen KL, et al. Methodological issues in therapeutic trials of COPD.

   Eur Respir J 2008;31:927-33. [↑](#endnote-ref-6)
7. SERETIDE reducerer faldet i lungefunktionen hos patienter med kronisk bronkitis. Ad in Dagens Medicin 2013;May 3:11–2. [↑](#endnote-ref-7)
8. Celli BR, Thomas NE, Anderson JA, et al. Effect of pharmacotherapy on rate of decline of lung function in chronic obstructive pulmonary disease: results from the TORCH study. Am J Respir Crit Care Med 2008;178:332–8. [↑](#endnote-ref-8)
9. Gøtzsche PC. Vildledende forskning og markedsføring. Ugeskr Læger 2014;176:373. [↑](#endnote-ref-9)
10. Englev E. Åbenhed og dialog er svaret. Ugeskr Læger 2014;176:373. [↑](#endnote-ref-10)
11. Vestbo J. Peter Gøtzsches påstande om videnskabelig artikel er usande. Ugeskr Læger 2014;176:475–6. [↑](#endnote-ref-11)
12. The TORCH Study Group. The TORCH (Towards a Revolution in COPD Health) survival study protocol.

    Eur Respir J 2004;24:206-10. [↑](#endnote-ref-12)
13. Suissa S, Ernst P, Vandemheen KL, et al. Methodological issues in therapeutic trials of COPD. Eur Respir J 2008;31:927–33. [↑](#endnote-ref-13)
14. <https://medstat.dk/> [↑](#endnote-ref-14)
15. Gøtzsche PC. Comment on: Nannini LJ, Poole P, Milan SJ, et al. Combined corticosteroid and long-acting beta2-agonist in one inhaler versus placebo for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2013;11:CD003794 (comment published 2021;Aug 5). [↑](#endnote-ref-15)
16. Gøtzsche PC. Comment on: [Why the Cochrane risk of bias tool should not include funding source as a standard item](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10897924/). Cochrane Library 2014;Jan 10. [↑](#endnote-ref-16)