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30 days in medicine

Drug companies withholding information on trial protocols

A study published in the *Journal of the Royal Society of Medicine* shows that half of commercially sponsored trial protocols contain redactions, meaning that drug companies are withholding information on trial protocols. The authors of the study requested access to 78 commercial and non-commercial trial protocols approved by a research ethics committee in Denmark from October 2012 to March 2013, under freedom of information rules. However, they found that access was difficult despite their assurances that individual trials would not be identified. It took 3 years to receive all 79 protocols, and Sanofi-Aventis took legal action. Other companies that withheld information included Merck Sharp & Dohme, Novo Nordisk, Bayer and GlaxoSmithKline. Only three companies supplied unredacted protocols – Abbott, Pfizer and Eli Lilly.

Eight of the protocols were excluded from the final results, showing that 17 of 34 protocols for commercially sponsored trials were not redacted, compared with 34 of 36 non-commercial trials. The protocol information most likely to be withheld was evidence of problems with the reliability of the data, such as data analysis, handling of missing data, detection and analysis of adverse events and premature termination of the study. The authors could not identify any legitimate rationale for the redactions, and commented that the amount of redactions in the protocols received was so large that they were rendered useless for assessing the ethical justification for the studies and for identifying discrepancies with subsequent publications.

Marquardsen M, Ogden M, Gøtzsche P. Redactions in protocols for drug trials: What industry sponsors concealed. J R Soc Med 2018 (epub 25 January 2018). https://doi.org/10.1177/0141076817750554

Drinking very hot tea linked to oesophageal cancer

Regularly drinking very hot tea, when combined with tobacco or alcohol use, is associated with an increased risk of oesophageal cancer, according to a Chinese study with more than 450 000 participants. However, the study, published in *Annals of Internal Medicine,* found no increased risk of oesophageal cancer in those who drank hot tea but did not smoke or regularly drink alcohol. Alcohol consumption and tobacco smoking are already well-established causes of oesophageal squamous cell cancer.

The prospective study included 456 155 people aged between 30 and 79 years from 10 areas across China. The participants in the study were asked how often they drank tea and whether they drank it warm, hot or boiling hot. They were also asked about smoking habits and whether they drank 15 g of alcohol or more a day – roughly two units, or a standard glass of wine.

During a median follow-up of 9.2 years there were 1 731 new cases of oesophageal cancer. Individuals who drank tea at a high temperature, drank alcohol regularly and smoked had an oesophageal cancer risk five times greater than those who had none of those three habits. The risk of oesophageal cancer was also increased for those who drank hot or burning hot tea if they either smoked or drank excessively.

Yu C, Tang H, Guo Y, et al. Effect of hot tea consumption and its interactions with alcohol and tobacco use on the risk of esophageal cancer: A population based cohort study. Ann Intern Med 2018 (epub 6 February 2018). https://doi.org/10.7326/M17-2000

Alcohol more dangerous to the brain than marijuana

Scientists at the University of Colorado Boulder conducted a review of existing imaging data that looked at the effects of alcohol and marijuana, or cannabis, on the brain. Their findings linked alcohol consumption with long-term changes to the structure of white matter and grey matter in the brain. However, the use of marijuana seemed to have no significant long-term effects on brain structure.

Study leader Rachel Thayer, of the Department of Psychology and Neuroscience at the University of Colorado Boulder, and colleagues recently reported their results in the journal *Addiction*.

Thayer RE, YorkWilliams S, Karoly HC, et al. Structural neuroimaging correlates of alcohol and cannabis use in adolescents and adults. Addiction 2017;112(12):2144-2154. https://doi.org/10.1111/add.13923

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