Archives of Virology (2022) 167:1725
https://doi.org/10.1007/s00705-022-05465-z

EDITORIAL

Editorial: Randomised clinical trials in Archives of Virology

Tim Skern[1]

Received: 25 April 2022 / Accepted: 25 April 2022 / Published online: 4 May 2022

Modern medicine is unimaginable without randomised clinical trials (RCTs). RCTs are however only as good as the initial randomisation of the participants in the trial or the statistical tools that are used to analyse the results. Unfortunately, some RCTs have been beset with problems as their underlying data might not exist [1, 2, 5]

What does this mean for Archives of Virology which occasionally publishes papers containing the results of RCTs? A recent retraction of one of those RCTs (Dabbous et al. 2021) shows the importance of assessing the trustworthiness of the underlying data, for example by examining the randomisation of the participants and the statistical analysis at the review stage. For instance, in this publication, a cursory glance at the means and standard deviations of some of the parameters would have revealed that, in several cases, the standard deviations were higher than the mean. Further, subtraction of the standard deviations from the mean would have resulted in negative numbers, which was simply not possible with the parameters being measured. How can 95% of the values lie within two standard deviations when there is a negative number? This should have been a flag to return the manuscript without review to the authors. Unfortunately, these discrepancies were missed by myself, the handling editor and the reviewers. Fortunately, a whistle-blower observed other problems with the statistics which led to a thorough examination of the underlying data that indicated that the study was impossible as reported and finally to a retraction of the paper.

It is crucial to learn from this episode. As a consequence, in the future, all clinical trials and large observational studies submitted to Archives of Virology must be accompanied by the raw data files so that the underlying data can be assessed on trustworthiness. If necessary, experts in statistics will be consulted to advise whether the underlying data are true and whether statistical analyses have been carried out correctly. Anonymized datasets underlying newly published RCTs will be available online as supplementary data. This should ensure that any future clinical trials in Archives of Virology are trustworthy, will fulfil the required standards and that their results will have value for the community.

Going back, all papers containing RCTs published in the journal will be retrospectively assessed for their trustworthiness including the quality of the randomisation and statistical analyses [3, 4]. If necessary, the papers will be investigated in detail and readers informed of their outcome.

I thank Professor Ben W. Mol (Monash University, Melbourne, Australia) for critical comments.

References

1. Bolland MJ, Avenell A, Gamble GD, Grey A (2016) Systematic review and statistical analysis of the integrity of 33 randomized controlled trials. Neurology 87:2391–2402
2. Bordewijk EM, Wang R, Askie LM, Gurrin LC, Thornton JG, van Wely M, Li W, Mol BW (2020) Data integrity of 35 randomised controlled trials in women' health. Eur J Obstet Gynecol Reprod Biol 249:72–83
3. Carlisle JB (2017) Data fabrication and other reasons for non-random sampling in 5087 randomised, controlled trials in anaesthetic and general medical journals. Anaesthesia 72:944–952
4. Carlisle JB (2021) False individual patient data and zombie randomised controlled trials submitted to Anaesthesia. Anaesthesia 76:472–479
5. Ioannidis JPA (2021) Hundreds of thousands of zombie randomised trials circulate among us. Anaesthesia 76:444–447

Handling Editor: Tim Skern.

✉ Tim Skern
timothy.skern@muv.ac.at

[1] Medical University of Vienna, Vienna, Austria