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**World record in number of P-values in a randomised clinical trial?**

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In a double-blind trial from Japan in 158 patients with rheumatoid arthritis comparing two nonsteroidal, anti-inflammatory drugs (NSAIDs), tolfenamic acid and indomethacin, 857 significance tests were reported.1 There were analyses of baseline data, multiple benefits and harms outcomes, subgroup analyses based on patient characteristics, control visits, etc.

A priori, one would not expect so see differences when two NSAIDs are being compared.2 If there are no true differences between the two drugs, one would expect 43 of the tests (5% of 857) to be statistically significant by chance (95% confidence interval 31 to 57). The authors found 48 significant results, which did not impress them, as they concluded that, “overall, general analysis of the cases did not indicate significant differences between the two groups.”

Excessive statistical testing in clinical trials, particularly without plausible, predefined null hypotheses, is inappropriate. Testing baseline data is particularly misleading, as we already know – given adequate randomisation – that any differences must be chance findings since randomisation is a chance procedure.3

**References**

1 Kawakami Y, Iwasaki Y, Fujimori I, et al. [Evaluation of GEA 6414 in the treatment of rheumatoid arthritis. A comparative double-blind study with indomethacin] (Japanese). Basic and Clinical Medicine 1981;15:445-72.

2 Gøtzsche PC. Bias in double-blind trials (summary of doctoral thesis). Dan Med Bull 1990;37:329-36.

3 [Altman DG](https://www.ncbi.nlm.nih.gov/pubmed/?term=Altman%20DG%5BAuthor%5D&cauthor=true&cauthor_uid=6405856), [Gore SM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Gore%20SM%5BAuthor%5D&cauthor=true&cauthor_uid=6405856), [Gardner MJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Gardner%20MJ%5BAuthor%5D&cauthor=true&cauthor_uid=6405856), [Pocock SJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Pocock%20SJ%5BAuthor%5D&cauthor=true&cauthor_uid=6405856). Statistical guidelines for contributors to medical journals.

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