

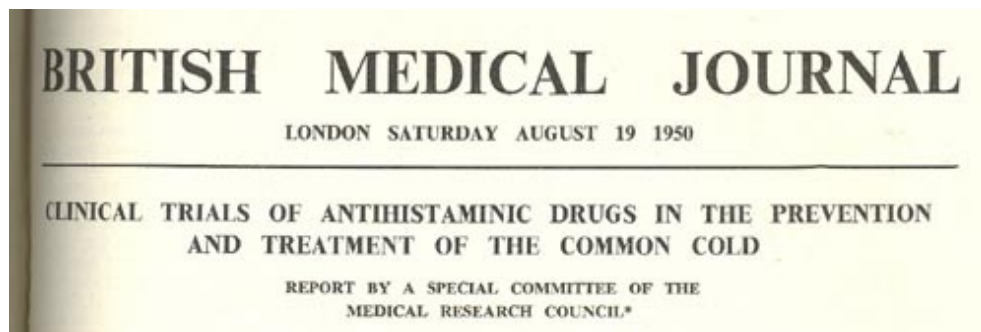
## Records

Key Passage(s)    Context

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**Medical Research Council (1950)**. Clinical trials of antihistaminic drugs in the prevention and treatment of the common cold. BMJ 2:425-431.

### Key passages



### Design of Trial

To ensure that no bias could enter into the assessment of results it was essential that neither the patient nor the investigator should be aware whether antihistaminic tablets or control tablets had been given in a particular case. For this purpose, those who were to be treated and those who were to be "controls" were prearranged in random order by the use of random sampling numbers, with the one restriction that each batch of 50 volunteers should include 25 treated (T) and 25 controls (C) (a restriction not known at the centres).

These lists were numbered consecutively, so that, for example, a series might run as follows : 1T, 2T, 3C, 4T, 5C, 6C, and so on, randomly. Such lists were constructed, in the Council's Statistical Research Unit, for each centre. Record sheets and cartons containing the appropriate tablets were then marked (in the Statistical Research Unit) with the serial number—namely, 1, 2, 3, 4, 5, 6, etc., but with no reference to (T) or (C)—and sent to the local centres; thus at the local centre one carton and one record sheet, *the serial numbers of which corresponded*, were used for each patient. They were used in strict order of serial number; thus if the last patient on one day was recorded on record sheet "15" and received tablets from carton "15," the first patient on the next day was recorded on record sheet "16" and received tablets from carton "16." The key to the identity of the serial numbers was kept centrally and secret until the end of the investigation.

This somewhat novel method was adopted in place of the more usual one of merely labelling one product X and the other Y and giving them in random order, in view of the side-effects to be expected with the antihistaminic drug. If decisive side-effects were observed with even one patient then the nature of X (and Y) would ever after be known (or suspected). With the method chosen the identity of one carton might well be suspected in the patient with side-effects, but no evidence would thereby be given regarding the treatment of any other patient.