The opportunities and challenges of pragmatic point-of-care randomised trials using routinely collected electronic records: evaluations of two exemplar trials

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Plain English summary

Evaluation of two randomised point-of-care trials

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Plain English summary

Doctors and the NHS have a duty to ensure that prescribed medicines are both safe and effective. A randomised trial is considered the best method to evaluate the effects of medicines. In a randomised trial one or more groups of patients receive different treatments or sometimes no treatment, in order to compare the results in the different groups. However, trials which compare different medicines that aim to do the same thing ('head-to-head comparisons') are not routinely done. Most general practitioners (GPs) use computers to keep their medical records. In this study we wanted to find out if it would be possible and useful for the NHS to use these electronic health records (EHRs) to carry out the research that is usually done in trials. We therefore carried out two small trials and interviewed NHS staff and patients. We found that GPs were required to fill in many forms, which took considerable time and effort, before being allowed to ask patients to take part in the trials. As a result, only about 5 out of 100 GPs completed all of the paperwork. Although most of the GPs expressed strong support for EHR trials, they did not have time for this extra paperwork. One trial recruited all the patients required, while the other trial only recruited one-fifth of its target. The 10 patients who were interviewed all said that being recruited into a trial during a consultation with their GP was acceptable, as was the use of their electronic health record for the trial. Our conclusion is that EHR trials are feasible but the burden of red tape needs to be reduced. The use of electronic records to undertake research could greatly simplify trials of medicines.

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