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COMMENTARY

Clinical trials: when to start and when to stop

See page 1486

In a Research letter in today's *Lancet*, V Gournay and colleagues describe three cases of severe hypoxaemia in a randomised trial of prophylactic ibuprofen for patent ductus arteriosus in premature infants. This reports provides one or two important reminders for trialists and clinicians.

The first reminder is that the right time to start a clinical trial is, as here, when the first patient is offered a new treatment strategy—a lesson that is still, all too often, ignored. New treatments, like cisapride for mild reflux, continue to come into widespread use in neonatal medicine without critical evaluation. It took a decade for the risk of arrhythmia to be widely recognised, and even longer for clinicians to realise that this drug did little to alleviate gastro-oesophageal reflux in most children.[1]

The second reminder is that the right time to stop a clinical trial is much less certain. Many feel that a trial should close as soon as a finding of statistical significance appears, but there have been many false dawns with this approach. A succession of strategies for preventing intraventricular haemorrhage in the preterm baby have come and gone in this way. Etamsylate, fresh-frozen plasma, indometacin, pancuronium, phenobarbital, and α-tocopherol have all been tried, and all had controlled trial evidence in their favour.[2] Unfortunately, modest incremental advances in care are seldom made on the basis of a single small trial. Only with indometacin did larger trials eventually confirm that early prophylaxis does cause a small but consistent decrease in the incidence of severe haemorrhage, although this decrease has little impact on the risk of death or disability.[3,4] Ibuprofen, another prostaglandin inhibitor, is now starting to be studied in much the same way.[5–7] This drug causes duct closure as effectively as indometacin.[8,9]

Clinicians are sometimes as easily enthused as the general public when some "breakthrough" is announced for a previously untreatable disorder. Changing practice is a slower process once a consensus has emerged over clinical management, and the study of what does, and does not, cause clinicians to adopt such change is still in its infancy. Many would now agree with Richard Doll[10] that such studies should only stop when "the trial evidence, combined with any other new evidence that had been reported since the trial began, would be sufficient to bring about a change in practice if reported to the profession in general". And, as he says, "there is no particular p value for that". It is certainly not 0·05. It may be closer to 0·001, but wisdom does not reside in any single abstract number.

It is against this background that today's Research letter needs to be read. On this occasion a trial has been stopped even before a statistical excess of adverse events occurred. The investigators could face criticism for this. *The Lancet* could also face criticism for making this fact known before any fuller report on the study's main outcome finds its way into print. Adverse events reported out of context can be seriously misleading—as happened during one early trial of oral tolbutamide for type 2 diabetes.[11] However, such delay clashes with the need to alert others, promptly, to a possible complication of early prophylaxis with ibuprofen.

The reported adverse events could have occurred by chance. Against that, a causal relation could easily go unrecognised in the very preterm baby, given the known lability of the pulmonary vasculature at this time. No such problem has yet been recognised with indometacin, but we already know that indometacin and ibuprofen affect cerebral, renal, and mesenteric blood-flow differently.[5] Prostaglandin activity peaks at this time,[12] so a problem of the type described by Gournay and colleagues has biological plausibility. In the only two earlier trials of very early prophylaxis with ibuprofen, 73 babies received active treatment, but both studies specifically excluded babies with persistent pulmonary hypertension, and only one attempted treatment within 6 h of birth.[13,14]

Treatment to achieve duct closure on the first day of life, without waiting for evidence of persisting patency, achieves nothing except a reduction in the number eventually requiring ligation.[4] It can also be dangerous when pulmonary artery pressure is high, or a duct-dependent heart defect exists.

EH has received commercial and public funding to collaborate in and undertake more than a dozen clinical trials in the past 30 years.

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