BRITISH TRANSPLANTATION SOCIETY
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A bleak future for transplantation clinical trials?

The future of large, industry-funded trials in specialties such as transplantation could be in jeopardy because of the increasing availability of generic drugs. This was the prediction of Professor Teun van Gelder, Erasmus Medical Centre, Rotterdam, during a workshop at the British Transplantation Society meeting.

'The worldwide shift from innovator to generic drugs inside and outside transplantation is forcing the pharmaceutical industry to make new choices and new strategies. Companies will select their markets very carefully for drug development, choosing those where current treatments are either ineffective or available only at high cost,' explained Professor van Gelder.

Neither of these factors applies to transplantation: current therapies are effective and cheaper, generic versions of most standard immunosuppressive drugs are now available. An additional dilemma is that organizations such as the National Institute for Health and Care Excellence (NICE) are unlikely to accept future new, more expensive drugs if they have relatively small benefits for patients compared to currently available treatments.

Professor van Gelder concluded: 'It is not necessarily the end of prospective industry-funded trials, but they will not be as frequent as in the past 10 years.'

Large, investigator-led clinical trials will continue to be feasible, but only if UK transplant units collaborate both within and outside the UK, according to Dr Richard Haynes of the Clinical Trial Service Unit and Epidemiological Studies Unit, Oxford.

Dr Haynes is a principal investigator on the Campath, Calcineurin inhibitor reduction and Chronic allograft nephropathy (3C study). This multicentre, open-label, randomized controlled trial includes 852 UK patients undergoing kidney transplantation. It is designed to compare alemtuzumab (Campath)-based induction therapy with basiliximab-based therapy, and sirolimus-based maintenance therapy with tacrolimus-based therapy from 6 months after transplantation.

Citing 3C as an example of national collaboration, Dr Haynes commented: 'We have managed to draw together 18 of the 23 adult kidney transplant centres in the UK. About 25% of patients transplanted during the recruitment phase were included in 3C. This is impressive and we can be reassured that our results will be representative and therefore generalisable to the UK.'

Five-year outcomes of 3C are expected by the end of 2014, but the study will continue to provide long-term data through cooperation with NHS Blood & Transplant, the UK Renal Registry, cancer registries and hospital episode statistics.

'Because of such registries, the UK may be uniquely placed to be at the heart of collaboration with partners around Europe and across the world,' concluded Dr Haynes.

Sue Lyon

Dr Richard Haynes, University Research Lecturer and Honorary Consultant Nephrologist, Clinical Trial Service Unit and Epidemiological Studies Unit, University of Oxford, Oxford

Research round-up, by Sue Lyon

High blood pressure no bar to living kidney donation

It is safe for people with well-controlled hypertension to donate a kidney, according to a study of 555 consecutive live donors. Of these, 50 had high blood pressure which was well controlled at baseline with at least one antihypertensive agent and without evidence of end-organ damage.

There were no differences between hypertensive and non-hypertensive donors in mean creatinine clearance at baseline (117.4 ml/min *vs* 109.4 ml/min; *P*=0.114) and at 5-year follow-up (92.5 ml/min *vs* 90.1 ml/min; *P*=0.762).

There was no evidence at 5 years of new-onset proteinuria in either group, and blood pressure remained well controlled in the hypertensive donors at 135/85 mmHg *vs* 135/81 mmHg in the non-hypertensive group (*P*=0.971 and 0.158).

Charif R et al (2014) Hypertension is not a contraindication to living kidney donation. Abstract 024

Fast-track scheme leads to more transplants

A new fast-track kidney allocation system has led to better use of declined kidneys and comparable outcomes to standard allocation kidneys. Between November 2012 and April 2013, 10 adult centres transplanted 85 of 124 fast-track kidney allocation system kidneys. The largest participating centre, accounting for 30% of total use, accepted 34 kidneys. Of these, 31 were allocated and 25 transplanted in 23 recipients (two dual transplants).

Six-month graft and patient survival were 95% and 100% respectively with median serum creatinine 150 µmol/litre at 3 months (interquartile range 79.0–322.0 µmol/litre). These outcomes were comparable to a matched group of standard kidneys transplanted during the same period.

White A et al (2014) Impact of new fast track kidney allocation scheme (FTKAS) for declined kidneys in the United Kingdom. Abstract 033

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