Reviewer's report

Title: Rationale and design of the balANZ trial: A randomised controlled trial of low GDP, neutral pH versus standard peritoneal dialysis solution for the preservation of residual renal function

Version: 1 Date: 17 June 2010

Reviewer: Nicholas Topley

Reviewer's report:

This is the first time I have had to review a clinical trial protocol for a journal, particularly for a trial that is completed (albeit having failed to recruit the target number of patients). I find myself, luke warm about it given it is the results that we want to see as the trial is effectively over. If one is to critique its design then despite the power calculation to me it is significantly underpowered for this patient population. The first author will know from his own ANZdata studies that this is in fact the case.

If one is to comment on the design, it is straightforward enough but one doubts that it will produce a clear cut result given the numbers recruited (i.e. half the target population). Would one design it any differently if one was doing it again today, probably not but the therapy still needs this type of study in sufficient numbers of patients. In reality we have probably missed the boat for the precise reason this trial "failed" i.e. that many nephrologists believe that biocompatible is better without hard evidence. It then becomes a simple economic choice, if its priced the same as conventional solutions all nephrologists will use the more biocompatible solution. To me its reasonably clear that observational cohort studies are really the only way we are going to address the questions this study was designed to answer.

Major compulsory revisions:

The discussion is weak, surely if this is to be published it should be as a blueprint to designing the perfect PD biocompatibility trial. This should be discussed as should be the reasons clinical and economic as to whether this will ever be achieved. If not what are the alternatives?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I declare that I have no competing interests