### **POSTER PRESENTATION**



**Open Access** 

# Analysis of continuous biochemical parameters in long-term trials of chronic disease where outcomes could be affected by further intervention

Natalie Ives<sup>1\*</sup>, Samir Mehta<sup>1</sup>, Elizabeth Brettell<sup>1</sup>, Marie Valente<sup>1</sup>, Sunil Bhandari<sup>2</sup>

*From* 3rd International Clinical Trials Methodology Conference Glasgow, UK. 16-17 November 2015

#### Background

Chronic kidney disease (CKD) affects 1 in 10 adults in the UK, and is an increasing burden on the NHS - dialysis costs ~£30,000/year. Key clinical outcomes in CKD are need for dialysis or transplantation and survival. However, designing trials with these endpoints requires large patient numbers. To reduce sample size requirements, trials have used measures of renal function (e.g. serum creatinine, glomerular filtration rate), which correlate with longer-term clinical outcomes. However, there are interpretation issues for these parameters if the rate of dialysis or transplant is affected by treatment group, as these interventions impact on renal function.

#### Methods

We plan to undertake a review of studies in stage 4/5 renal disease to assess analysis methods used. Have trials excluded patients from the analysis when they start dialysis or have a transplant, or if they are included, what methods have been used to account for this or potential data missing not at random. Possible options include last observation carried forward, flat value or multiple imputation. Based on this review, we plan to assess the different analysis methods in terms how results may vary and which provides the most robust result.

#### Results

The results will inform the statistical analysis plan for the STOP-ACEi trial (funded by NIHR EME) assessing withdrawal of ACE-inhibitors and Angiotensin Receptor Blockers in patients with advanced CKD.

<sup>1</sup>University of Birmingham, Birmingham, UK

Full list of author information is available at the end of the article

#### Conclusions

Although this example relates to renal disease, there are other areas where continuous outcomes are used in trials, where other factors may influence or impact on this outcome.

#### Authors' details

 $^1 \rm University$  of Birmingham, Birmingham, UK.  $^2 \rm Hull$  and East Yorkshire Hospitals NHS Trust, Hull, UK.

Published: 16 November 2015

doi:10.1186/1745-6215-16-S2-P62 **Cite this article as:** Ives *et al.*: Analysis of continuous biochemical parameters in long-term trials of chronic disease where outcomes could be affected by further intervention. *Trials* 2015 16(Suppl 2):P62.

## Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

**BioMed** Central

Submit your manuscript at www.biomedcentral.com/submit



© 2015 lves et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http:// creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/ zero/1.0/) applies to the data made available in this article, unless otherwise stated.