Author's response to reviews

Title: A Randomised Study of Temporary Epicardial Cardiac Resynchronisation Versus Conventional Right Ventricular Pacing in Cardiac Surgical Patients.

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Author's response to reviews: see over
Dear Editor,

I have attached version 5 of our protocol. This includes a minor change on pages 13 to the doses of agents used during induction of anaesthesia.

Please accept my apology of an inconvenience this may cause.

Yours sincerely,

Dr Stuart Russell.

Title: ‘A randomised study of temporary epicardial cardiac resynchronisation versus conventional right ventricular pacing in cardiac surgical patients.

Thank you for considering this clinical trial protocol for publication in your journal. The manuscript is for a temporary pacing trial after cardiac surgery. The aim of the study is to evaluate the clinical and haemodynamic effects of temporary biventricular pacing (aka cardiac resynchronisation) after cardiac surgery in subjects with severe left ventricular impairment (ejection fraction no more than 35%).

The primary endpoint for this trial is the duration of level 3 care required after cardiac surgery. In brief, this is the requirement for multi-organ support or more than one
inotrope, vaso-active infusion or mechanical circulatory support (intra aortic balloon pump). We believe that this measurement is of greater clinical value than the total length of ITU stay, which is less clearly defined and dependent on none clinical factors.

In addition, our protocol investigates the haemodynamic effect of optimising the atrioventricular and interventricular delays. Previous studies of permanent pacing have reported that optimisation improves cardiac output; however limited evidence is available in the immediate post operative setting.

In order to optimise the biventricular pacing, a dedicated triple site, temporary pacemaker was used. To our knowledge there is only one manufacturer of this type of device and no previous publications of its clinical application. Previous studies have either adapted a permanent biventricular pacing system or temporary dual port system.

We would be grateful for any advice or suggestions from either the editorial team or external reviewers. Please let me know if you require any further information.

Yours sincerely,

Dr Stuart Russell.

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