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# Update: Rationale and design of the Sodium Lowering In Dialysate (SoLID) trial: a randomised controlled trial of low versus standard dialysate sodium concentration during hemodialysis for regression of left ventricular mass

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## Abstract

After the publication of our paper Dunlop et al. "Rationale and design of the Sodium Lowering In Dialysate (SoLID) trial: a randomised controlled trial of low versus standard dialysate sodium concentration during hemodialysis for regression of left ventricular mass", we became aware of further data correlating left ventricular (LV) mass index at baseline and their corresponding mass at 12 months, using cardiac magnetic resonance imaging (MRI) in patients on hemodialysis. The original published sample size for the SoLID trial of 118 was a conservative estimate, calculated using analysis of covariance and a within person Pearson's correlation for LV mass index of 0.75. New data communicated to the SoLID trial group has resulted in re-calculation of the sample size, based upon a within person Pearson's correlation of 0.8 but otherwise unchanged assumptions. As a result, the SoLID trial will now recruit 96 participants.

## Update

After the publication of our paper Dunlop et al. "Rationale and design of the Sodium Lowering In Dialysate (SoLID) trial: a randomised controlled trial of low versus standard dialysate sodium concentration during hemodialysis for regression of left ventricular mass" [1], we became aware of further data correlating left ventricular (LV) mass index at baseline and their corresponding mass at 12 months, using cardiac magnetic resonance imaging (MRI) in patients on hemodialysis.

The original published sample size for the SoLID trial of 118 was a conservative estimate, calculated using repeated-measures analysis of covariance (ANCOVA) and a within person Pearson's correlation for LV mass index of 0.75.

The assumption of a correlation of 0.75 was based on private communication from the Jardine group (private communication P Mark 8/2/2011) [2–4]: in a cohort of 59 patients of their patients with repeated measures of LVMI at least 6 months apart (using cardiac MRI), correlation was 0.87 ( $p < 0.001$ ) with normally distributed data. Modelling these data, and allowing for 25 % for drop outs, it was determined that 59 participants would be enrolled in each arm (power 0.8, alpha 0.05).

New data communicated to the SoLID trial group has resulted in us re-calculating sample size for the SoLID trial (private communication C McIntyre and A Odudu 30/4/2014) [5]: in a cohort of 44 patients of their patients with repeated measures of LV mass index 12 months apart (using cardiac MRI), correlation was 0.81 ( $p < 0.001$ ). In 21 of these patients, there was an intervention that might have modestly affected their LV mass index; however, restricting analysis to the 23 paired values in the control group provides a similar correlation of 0.83.

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Based on the data above, the sample size has been recalculated using a within person correlation of 0.8, but otherwise unchanged assumptions. It is determined that 48 participants will be enrolled in each arm. The change in sample size has been approved by the National (New Zealand) Multi-region Ethics Committee (IRB00004663) of the New Zealand Ministry of Health (IORG0000895), and the primary funding body for this study the Health Research Council of New Zealand.

#### Competing interests

The authors declare that they have no competing interests.

#### Authors' contributions

JLD participated in the trial design, and drafted the manuscript. ACV participated in the trial design, developed the statistical plan, and helped to draft the manuscript. MRM conceived and developed the trial, and participated in the statistical plan and helped to draft the manuscript. RSG, IAH, and DORM participated in design and development of the trial, and helped to draft the manuscript. JRdZ and PJM participated in the trial design and coordination, and helped to draft the manuscript. CJH, KSR, and DJS participated in the trial coordination and implementation, and helped to draft the manuscript. All authors read and approved the final manuscript.

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