Reviewer's report

Title: European trial of free LLight chain removal by exTEned haemodialysis in cast nephropathy (EuLITE): a randomised control trial

Version: 2 Date: 4 August 2008

Reviewer: gordon doig

Reviewer's report:

Please provide additional details such that subjective decision points regarding the analysis are appropriately described prior to undertaking the analysis. Expansion of other areas of this protocol paper would provide improved understanding of the key methodological aspects of this trial.

1. Please provide additional information regarding the random sequence generation. How was it generated? What program was used? Was blocking or stratification employed? If so, what size blocks?

2. Additional explicit details regarding how allocation concealment was maintained via ‘central randomisation’ are required.

3. A description of the eCRFs would be welcomed. Are they web based or local computer programs? What program/database are they native to?

4. In the sample size calculations, the authors indicate they expect to experience ‘drop outs’. When is a patient allowed to ‘drop out’? Do investigators make the decision to ‘drop’ a patient from the study? Please describe whether it was intended to follow ‘drop outs’ to Day 90. What assumptions will be made regarding ‘lost’ patients to maintain the integrity of the ITT analysis of the primary outcome? For example, will you assume all ‘lost’ patients had a bad outcome? What assumptions will be made regarding missing data for other secondary outcomes?

5. With regards to the statistical analysis, what factors will be tested to investigate ‘baseline balance’? What p-value threshold will be used to indicate the presence of baseline balance?

6. Please be more specific in your reference to statistical testing of your primary outcome. Will a ‘relative risk’ test or a ‘chi-square’ test
serve as the primary analysis of the primary outcome? Which specific ‘relative risk’ test will be used? What type of ‘chi-square’ test? Mantel-Haenszel chi-square, continuity adjusted chi-square? What analysis will be undertaken if baseline imbalance is detected?

7. How will ‘the mean pre-dialysis sFLC concentrations for days 4-6 etc’ be compared with pre-randomisation levels? Signed Rank Sum tests or paired t-tests? How will the assumption of normality be tested? Will this analysis be adjusted for multiple comparisons? Is there a better way to compare these values between groups as opposed to within each