Reviewer's report

Title: Risk factors for foot ulceration in adults with end-stage renal disease on dialysis: study protocol for a prospective observational cohort study

Version: Date: 27 March 2015

Reviewer: Keith McCormick

Reviewer's report:

This is a well-planned and timely protocol for a prospective observational cohort study to identify risk factors for foot ulceration in individuals with end-stage renal disease on dialysis. The study already has the appropriate approvals including ethical approval from La Trobe University and the three participating health organisations.

In my opinion the Protocol is publishable with only minor changes and the following suggestions/comments should be seen as discretionary revisions which the authors can address, if they feel the protocol could be enhanced by doing so. As the study has started already (baseline data collection Jan to Dec 2014) – it may not be possible to address some of the points below.

Comments, questions and observations:

• Did the authors consider including ankle range of motion (dorsiflexion) in the biomechanical assessment?

• The laboratory blood tests listed in Table 1 do not appear in the methods/design section. It might have been interesting to also look at cholesterol and triglycerides in addition to the other blood tests cited

• Did the authors consider including a neuropathy symptoms score or neuropathy disability score in addition to vibration perception and monofilament scores

• As this is a multi-centre trial, did authors identify specific individuals to conduct the clinical tests and what training was provided to reduce bias and ensure parity in the accurate use of instrumentation? Were specific standard operating procedure (SOP) documents provided to researchers for each of the tests?

• You mention a reliability study of 20 participants in the abstract but there is no protocol for this in the method/design section – will it address inter-tester reliability, will you be repeating the same test twice at certain intervals with study participants? What specific statistical analysis will be used (e.g. coefficient of variance)? It is important to include more detail here

• For your vascular studies (ABPI and toe pressures) in addition to maintaining the room temp (21-23°) you need to rest your patients in a supine position for at least 15 minutes – was this done?

• I think it would be of great value to revisit the cohort again after 3 years, even with a reduced protocol or just to collect mortality data. There is an interesting
Kaplan Meier plot (stratified by number of risk factors) in a recent paper by Jones et al (2012) which shows how cumulative survival (haemodialysis population) drops off considerably after 24 months in the group of individuals with 2 of 3 identified risk factors (peripheral neuropathy, peripheral arterial disease or foot pathology)- although there are some clear limitations with this study it does demonstrate the possibility of enhancing your findings by considering a 36 month follow up. It will also be interesting to review the data stratified by diabetes status – this could support emerging data that all individuals with end stage renal disease are at significant risk.

I am grateful for the opportunity to review this protocol which is of great interest to me. I look forward to seeing the results from this study which should provide greater insight to the scientific community on the risk factors for individuals with end stage renal disease on dialysis.


**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests