Reviewer’s report

Title: Wound Healing In Surgery for Trauma (WHIST): statistical analysis plan for a randomised controlled trial comparing standard wound management with negative pressure wound therapy

Version: 0 Date: 05 Nov 2018

Reviewer: Cynthia Bell

Reviewer’s report:

Clearly written and appropriate statistical analysis for the soon to be completed WHIST multi-site RCT comparing negative pressure wound care to standard care in lower limb fractures. There are only a few clarifications I would like to see addressed:

- Page 11, paragraph 207 - Only wound location is discussed as a potential covariate to investigate in secondary analysis given that the primary outcome is different between treatment groups. In reality, won't the investigators also consider other covariate effects from Table 2 such as antibiotic prophylaxis, how closed, etc?

- In the primary analysis of deep infection rate @30 days, all adjustments are made by random effects (site, open vs closed, ISS level, age, and gender) but why are open v closed, ISS, age and gender included as fixed effects in the secondary outcome models? Also, why are age and gender included in the models at all?

- Page 12, line 233 "non-parametric equivalent" - assuming Rank Sum but please specify.

- Page 12-13, lines 235-239 It is not clear how you plan to use the coefficients from the mixed effects linear regression model to compute AUC scores or estimate recovery time. Please include more details explaining this analysis. If switching to binary outcomes of DRI and EQ-5D please indicate threshold values as have been included in the description of the other secondary outcomes.

- Secondary (binary?) outcome POSAS is not discussed in the analysis section.

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