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: 04 Dec 2018

Reviewer: Mantaj Brar

Reviewer’s report:

A very detailed and thoughtful description of an analysis plan for a multi-centre parallel-group randomized superiority trial evaluating NPWT in lower-limb traumatic fractures. A couple of minor comments:

1) Which dataset will be used to compare AUC summary statistics for DRI and EQ-5D between groups - ITT with imputed or available data sets?

2) In the adjusted models, age and gender are included without any justification; certainly given the size of the trial would not expect a difference in these baseline covariates by random chance, and no evidence is presented that suggests gender or age in this patient population is associated with deep SSI rates. Conversely, it is conceivable QOL or disability measures may be associated with age and/or gender. Given the predicted event rate, I do not believe the inclusion of these two covariates would adversely alter (or improve) estimation of the treatment effect on the primary outcome. Please comment.

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Statistical review
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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