Cover

Official Title of Study: Prevention of Pressure Injuries During Aeromedical Evacuation or Prolonged Field Care

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Statistical Analysis Plan This study proposes to compare the effect of presence or absence of a Mepilex dressing) on variables (IL-1α/TP, TcPO2, interface pressure, skin temperature and moisture) potentially reflecting the modified effects of pressure, shear and microclimate associated with lying for an interval of (120 minutes) on either a standard NATO litter with mattress or a VSB. Primary analyses will contrast the Mepilex and non-Mepilex dressing groups, WITHIN the two support platform strata. That is, the two contrasts LITTER + Mattress (Mepilex vs. not) and VSB (Mepilex vs. not) will be the analysis foci. Analyses of the effect of support platform, and the interactions of platform with presence/absence of Mepilex pad will be considered secondary and exploratory. The statistical tests will be based on a group (Mepilex vs. non-Mepilex) by time (first sample – unloaded baseline, second sample post 120-minute loading) analysis. Analysis options depending on data structure include a repeated measures Group x Time ANOVA, an ANCOVA-based group analysis of the post-loading measurement controlled for the pre-loading measurement, a group analysis of the simple change score (post-loading – preloading), and a longitudinal analysis of the two-time points by group using Generalized Estimating Equations or a Linear Mixed Models. It is important to note that several of the studies using IL-1α as a dependent variable have used non-parametric statistical tests. Similarly, error bar plots in published papers document a degree of heteroscedasticity, with the variability in a batch apparently having considerable dependence on its mean. This potential non-normality problem may be met with data transformation (e.g., square root or logarithmic transform) to an appropriate carrier or use of Generalized Linear Models with an appropriate non-linear monotonic link function, or the use of non-parametric statistics. As an example of application of the last method to the current data structures, the simple change score or residual change score from pre- to post- loading could be analyzed with the non-parametric Mann-Whitney U test. Power Analysis: The a priori justification of group sample size with respect to statistical power will be based on the potential change in the variable (IL-1α/Total ratio), which is measured in each participant immediately before and after lying for 120 minutes on the support platform. The analyses of other variables (e.g., TCPO2, interface pressure, skin temperature/moisture) will be treated as descriptive and secondary. When there is limited evidence in the literature that bear directly on the estimation of an effect size in planning a preliminary study, several authors and agencies have argued for setting the sample size per group N per group = 12.76-78 Assuming two tailed two independent group comparisons, with an adjusted significance threshold set to alpha = 0.025 to accommodate multiple testing at the alpha = 0.05 level for both the NATO litter and the “VSB” strata, and the size of each group N = 12, the minimum Cohen’s d effect size per test necessary to achieve statistical power P = 0.80 is d = 1.336, which is considered a very large and ambitious effect size. However, there is related support in the literature that this level of effect is achievable using the proposed protocol. Hemmes55 (see Fig. 3, page 86, and Table A1, page 88) demonstrated that lying on either a rigid or soft-layered spineboard for 60 minutes raised mean sacral IL-1α/TP ratio by more than a factor of 10. de Wert24 (see Fig. 4A, page 510), using a 30- minute pressure and shear loading protocol on the forearm, showed that the presence of a Mepilex dressing resulted in IL-1α/TP ratio levels that were on the order of 7 times smaller than the “no dressing” condition.