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1st May 2013

Mr M Sukeik
Clinical Research Fellow
Department of Trauma & Orthopaedics
University College London Hospital
235 Euston Road
London NW1 2BU

Dear Mr Sukeik,

Re: A randomised controlled trial of Polyglactin 910 Triclosan coated sutures versus standard Polyglactin 910 sutures in patients aged 16 or over undergoing primary unilateral hip and knee arthroplasties in the department of trauma and orthopaedics at University College London Hospital

I confirm that you have taken statistical advice on this study. The study is a single-centred, double-blinded randomised controlled trial (RCT) of Polyglactin 910 Triclosan coated sutures versus standard Polyglactin 910 sutures. The primary outcome is the binary variable ASEPSIS score ten and below versus score 11 and over. Sample size calculations were performed under the following assumptions: a two group RCT with equal group sizes, 90% of patients on the uncoated suture to have a score of ten and below and 97.5% of patients with the coated suture to have a score of 10 and below, two sided 5% significance, 80% power, and 10% dropout. 210 patients are required in each group.

Recruitment and progress through the study will be summarised using a Consort diagram. The two study groups will be checked for comparability by comparing the baseline characteristics of the patients using means and standard deviations (or medians and inter-quartile ranges as appropriate) for continuous data and frequency counts and percentages for categorical data. The primary outcome will be analysed with a chi-squared test for a 2x2 contingency table or a Fisher's Exact test, as appropriate. If the two study groups prove not to be comparable then the primary outcome will be analysed with logistic regression including the baseline characteristics as co-variates. The primary outcome score will also be analysed with the Mann-Whitney U test as a secondary sensitivity analysis. Continuous secondary outcomes will be analysed with two sample t-test or Mann-Whitney U test according to the normality of data distribution. Categorical secondary outcomes will be analysed with a chi-squared test or Fisher exact test. The proportion of dropouts from the study will be reported together with a summary of reasons for dropout. Adverse events will be reported similarly. Data analysis will be done on an intention to treat basis. You will analyse the study yourself, in SPSS 14.

Yours sincerely

Mrs Pauline A Rogers, MSc CStat(retired)