Reviewer’s report

Title: The effect of triclosan coated sutures on rate of Surgical Site Infection after hip and knee replacement: A protocol for a double-blind randomised controlled trial.

Version: 1 Date: 2 April 2014

Reviewer: Julie J Bruce

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There are no page numbers or line numbers on the manuscript.

• Abstract – state that the primary outcome is superficial SSI. States in abstract that the study is a single-centre yet later refers to multiple hospitals. Clarify.
• Background – sentence starting ‘Over the past decade…’— incorrect use of semi-colons, colons (minor comment).
• Background - Refer to SSI as a single complication but the rates do differ by superficial vs deep. Also challenges of measurement in community setting given that majority of patients discharged home before infection presents.
• Methods – 2 centres mentioned here. Does not mention how long the trial will run for (how long funded for? Industry funded study?), also all participant recruitment has been completed. Although now in follow-up, unclear whether this is for HES data or what. Clarify. Assume also is for secondary outcome of deep SSI – how is this being collected? Observation of wound over the 12 month period?.
• Inclusion criteria – any age/ sex or were age limits applied? Any previous infection or signs of infection on admission (e. history of MRSA)
• Participant recruitment – I realise the challenge of changing tenses but in places it reads as though the trial is just about to start.
• Quasi-RCT & explains rationale for this approach. Thus a hospital administered either intervention or control sutures to all operated patients for the whole month.
• Clearly states primary outcome is superficial SSI ‘within 30 days of surgery’. However no information on how this was captured (assuming that all patients must have reached /completed 30 day assessment by now).
  o Who collects the data and how? GP records, self-report by patients, telephone calls by RAs….what efforts are made to record infections? If self-report, how will this be validated against researcher diagnosed infection? Similarly for 12 month infection. Given that this is the primary outcome, more information is needed here.
• Very vague re preoperative patient factors. Need to be specific here as potential for data dredging. Are you adjusting for the known risk factors for SSI? Eg. ASA grade etc. Again, significant literature on SSI risk factors post implant & whether you are adjusting for these.
• Other postoperative complications - are these are secondary outcomes – if so, how will they be captured as not all will be reliably recorded on HES.

• Delay to surgery – define what is meant by this. Time from assessment by surgeon / time from being added to list to surgery date / delay after admission – is unclear.

• No reference to SPIRIT 2013 Checklist which all trial protocols should now adhere to – think probably worth checking against this & structuring accordingly.

• These are all relative minor comments but think they need to be addressed before publication.