Author's response to reviews

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.

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Author's response to reviews: see over
Dear Editor,

Please consider our study protocol for publication protocol following revision.

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.

Reviewer: Mohammad-Reza Rasouli
Reviewer's report:
There are some issues about the manuscript:
• Abstract 2nd line: Please spell out NHS.
This has been clarified.

Introduction

• The authors described statistics from UK and Wales at the beginning of the introduction but reported projection in the number of TJA from the study by Kurtz et al which is based on the US data. It is better the authors specifically describe that this prediction is related to the US (might not be true in other countries).
This has been clarified.

• Although the exact rate of SSI is not clear and varies based on the definition, duration of follow up and many other factors, 3% rate of SSI following TJA is one of the highest reported rates in the literature. It is better the authors report a range for SSI based on the available literature.
This has been altered to more fairly reflect the current rate, with reference(1).

• Again, please spell out NHS when you write it for the first time in the text.
This has been clarified.

• The authors need to cite appropriate references in the introduction supporting their statements. No reference has been cited for some of the sentences in the introduction.
Additional ref have been added.

• Last paragraph of the introduction, the aim of this protocol is to describe design of a randomized controlled trial to test if triclosan coated sutures are able to decrease rate of SSI following TJA. Please edit it.
Replaced by: The aim of this trial is to determine if using a triclosan coated suture can significantly reduce the rate of superficial SSI at 30 days after primary TKR or THR.

Methods

• Is this study part of the “Northumbria Arthroplasty Suture Study (NASS)” If so, the protocol of that RCT has already been registered and it is not clear why the
authors want to register the protocol of this study separately. Please clarify it. This has been clarified: the ISRCTN is simply the registration and the full protocol has not been published.

• As I understood, the authors aim to adjust the results of logistic regression analysis only for patient age and gender. I recommend authors to adjust the multivariate model for patient’s comorbidity, TKA vs THA and other potential risk factors of SSI. This has been altered to a multivariate model, inc co-morbidity.

• Manuscript will benefit from linguistic editing. This has been re read and is now clear.


Reviewer: Julie J Bruce

Reviewer's report:

There are no page numbers or line numbers on the manuscript. Now added to manuscript

• Abstract – state that the primary outcome is superficial SSI. States in abstract Superficial added.

that the study is a single-centre yet later refers to multiple hospitals. Clarify. Clarified

• Background – sentence starting ‘Over the past decade….– incorrect use of semi-colons, colons (minor comment). Corrected

• 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. Clarified in Methods

• 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) Clarified

• Participant recruitment – I realise the challenge of changing tenses but in places it reads as though the trial is just about to start. Altered
• Quasi-RCT & explains rationale for this approach. Thus a hospital administered either intervention or control sutures to all operated patients for the whole month.  
**Correct**

• 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).

**Clarified with info on the 30 day HPA questionnaire**

  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.

**Further defined based on HPA criteria.**

• 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.  
**Addressed with info on multi-variant logistic regression analysis, adjusting for pre operative factors will be performed.**

• Other postoperative complications - are these are secondary outcomes – if so, how will they be captured as not all will be reliably recorded on HES.

**Information on collection added**

• 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.

**Clarified**

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

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