Author’s response to reviews

Title: Assessing the effectiveness of Dialkylcarbamoylchloride (DACC) coated post-operative dressings versus standard care in the prevention of Surgical Site Infection in clean or clean-contaminated, vascular surgery (the DRESSINg trial): study protocol for a pilot feasibility randomised controlled trial.

Authors:

Joshua Totty (hy9jpt@hym.ac.uk)
Amy Harwood (amy.harwood@hey.nhs.uk)
Paris Cai (paris.cai@hey.nhs.uk)
Louise Hitchman (louise.hitchman@hey.nhs.uk)
George Smith (georgeedsmith@gmail.com)
Ian Chetter (ian.chter@hey.nhs.uk)

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Reviewer #1: The investigators describe a pilot trial to measure the effectiveness of dialkyl carbamolynchloride (DACC) coated poste operative dressings to prevent surgical site infection in vascular surgery. I have the following comments.

The title is long and repetitive. "Randomized controlled trial" is mentioned twice.

We thank the reviewer for their comment, and we have adjusted the title accordingly. We hope that this suffices.

In the abstract, it is not clear how this is a pilot study. No pilot or feasibility measures are mentioned.

Thank you for your comment. We have added in details of the feasibility aspect of this trial.

Please provide a reference for "SSI's occur in at least 5% [2] of patients and have a significant impact on patient morbidity, mortality and have subsequent time and cost implications".
We thank the reviewer for their comments. An additional reference for this information has been added. The subsequent references have been amended to reflect this (line 70).

Please provide a reference for "DACC coated dressings are available on the open market in both the United Kingdom via the NHS supply chain, and the United States of America."

We thank the reviewer for their comments. An additional reference for this information has been added. The subsequent references have been amended to reflect this (line 91).

Write NHS in full at first use.
This has been amended accordingly.

In the methods section a hypothesis is reported (The main hypothesis is that post-operative wound dressing with a DACC-coated dressing reduces the rate of surgical site infection) which is contrary to the philosophy of pilot studies. They are not meant to test effectiveness of interventions.

We thank the reviewer for their comments. This has been removed to reflect this.

Please provide a justification for the inclusion/ exclusion criteria. For example the reason for this one is not obvious: "Patients undergoing carotid endarterectomy".

We thank the reviewer for their comments. We have included rationale for the quoted exclusion criteria (Line 126-127). However we feel the others, such as able to understand the information sheets, able to provide informed consent, are standard amongst most clinical trials and therefore would not require specific justification.

Feasibility outcomes are stated in the outcomes section. For a pilot study, these are the main outcomes and should therefore be part of the objectives.

We thank the reviewer for their comments. The objectives section states “The aim of this pilot randomised trial is to evaluate the feasibility of conducting a fully-powered randomised controlled trial” and therefore encompasses all of the feasibility outcomes stated in the outcomes section. These specific outcomes are better placed in a section titled outcomes than in the objectives section.
The first feasibility outcome is problematic. The use of data from pilot studies may give misleading estimates for sample size estimation. Caution is advised.

We thank the reviewer for their comments. The wording has been amended to state “contribute to” rather than “inform” the power calculation (Line 155). This data will be combined with other studies in order to produce a power calculation.

A few abbreviations are not defined at first use: ASEPSI, CDC, EQ-5D-3L, ICH, GCP. Also provide references for them

We thank the reviewer for their comments. ASEPSIS is not an abbreviation but the name of a tool (see references). CDC has been expanded at first use (Line 66). EQ-5D has been expanded (Line 180). ICH GCP has been expanded (Line 336-338). References already exist for ASEPSIS and CDC definitions (References 18 and 19). References have been added for ICH GCP (reference 30).

The sample size approach is good. It should be stated upfront that you have chosen a fraction of the sample size for the larger trial.

We thank the reviewer for their comments. This has been added to the objectives section (Line 122)

Please provide a reference for SPSS.

This has been added (Line 312-313)

Please list the confounding variables of interest.

These have been added (Line 321-322)

State how the data from this trial will inform a larger trial: How are you going to (cautiously) use the data from this trial to compute sample size estimates for a larger trial?
A small segment has been added to reflect this. (Line 240-242).

What criteria will you use to determine that a larger trial is feasible?

In the analysis plan, SSI is stated as the primary outcome. This shouldn't be the case for a feasibility study

No mention is made of how the feasibility criteria will be analysed or what thresholds will be used.

We thank the reviewer for their comments. The analysis plan has been amended to reflect how these will be analysed and interpreted (Line 312-318)

The trial registration does not have any feasibility outcomes: https://clinicaltrials.gov/ct2/show/NCT02992951

We thank you for this observation; This has been amended and will be updated in due course.

Reviewer #2: Introduction - "DACC coated dressings are available on the open market in both the United Kingdom via the NHS supply chain, and the United States of America". Can you please provide a more detailed description of DACC?

We thank the reviewer for their comments, and draw their attention to lines 100-108, where DACC is discussed in detail, including its mechanism of action and organisms against which it is effective.

Exclusion criteria- "Inability to give informed consent due to incapacity (as defined by the MCA 2005)". Could you please include a brief explanation about the MCA 2005 definition?

A reference has been added that links to the full guidance (reference 18).

Methods - "Hair removal (clipping) and anaesthesia will be conducted according to local hospital policy". Could you please include a brief explanation about the hospital policy?
Methods - Can you provide a more detailed description of how 'Clinical Review of Wound' will be performed at day 30 post op, 3 months post op, and 3 months post op. Also, can you please include an explanation about the validity of SF-36, EQ-5D-3L and Hpa Surgical Wound Healing Post Discharge Questionnaire?

We thank the reviewer for their comments, and draw their attention to lines 293-301, where the exact process for wound reviews is detailed. The requested information about the Quality of life tools used has been added in a section titled “Quality of Life assessments” (Line 212 – 217)