Author’s response to reviews

Title: Measuring skin necrosis in a randomised controlled feasibility trial of heat preconditioning on wound healing after reconstructive breast surgery; study protocol and statistical analysis plan for the PREHEAT trial

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Version: 1 Date: 22 Sep 2017

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We thank the editor for their review and enclose our responses to the queries raised below.

Query (i) page 6, line 150: why has a temperature of 43 degrees C being chosen - no justification given;

Author response: The heating procedure used is based on the protocol used in our phase 1 study and an experimental animal model investigating the effect of local heat preconditioning. A temperature of 43°C provides heat application to a supraphysiological level without causing a burn. We have added these details which justify the temperature to the section in question in the manuscript.

Query (ii) Will covering the bottle - e.g. with a cover, not reduce this temperature, and furthermore, the reduction of temperature will depend on the material of the cover

Author response: An interface could potentially reduce the heat that is being delivered to the skin, this is something we are looking at and will develop with further studies. As detailed in the intervention section all participants are provided with the same hot water bottle for use in the current study.

Query (iii) page 8, line 179: Is training provided as regards how to measure the area of the primary outcome - as measuring area of irregular shapes is not necessarily easy and so measure of accuracy should be noted.”
Author response: Training is given to all outcome assessors on the assessment protocol. We are using previously published and accepted methods of measuring the wound area using the SKIN score and clear graph acetates. This is being strictly adhered to and is working very well. We have added these details to the section in question in the manuscript.

We agree that measuring area of irregular shapes is not always easy which is why area will be measured independently by two assessors. As detailed in the manuscript we will assess the level of agreement between the two assessors measurements to establish whether this outcome would be suitable in a larger confirmatory clinical trial.