SESSION PROPOSAL 12

THE ASPIRE GUIDANCE ON SURGICAL PLACEBO CONTROLS IN RANDOMISED TRIALS

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Description of Session:

Background:

Placebo controlled randomised trials are generally considered the optimal trial design to investigate healthcare interventions. Having a placebo control potentially addresses a number of biases which could affect the observed effect. Their use outside of pharmacology is limited and this is particularly true for trials evaluating surgical procedures. Perhaps surprisingly surgical placebos have a history in randomised trials dating back to the 1950s. However, their use is highly controversial for ethical and design reasons and trials using them are relatively rare. Recently there has been increased interest in their conduct and a number of high profile trials (e.g. ORBITA, a surgical placebo trial of stenting for stable angina, and CSAW, a trial of sub-acromial decompression for shoulder pain). In this session we will present findings from the new ASPIRE (Applying Surgical Placebo In Randomised Evaluations) guidance on the use of placebo surgical in randomised trials and the related checklist developed by an international group of methodologists, trialists, ethicists and surgeons. Additionally, related work which provides an up to date review of current practice and the limitations in it will also be presented.

Invited session outline:

Session Chair - Dean Fergusson – Introduction to the session

Talk 1 (David Beard) – New insights on designing a placebo surgical trial The latest thinking and understanding of the placebo phenomenon in surgery will be covered in the initial presentation along with an outline of the session. This presentation will address the key principles of the ASPIRE guidance on how to design a surgical trial with a placebo control. It will address issues such as fidelity to the real procedure, mitigation of risk and related ethical and conduct issues.

Talk 2 (Sian Cousins) – When & how have placebo trials been used? Results of a systematic review examining key methodological issues will be presented in this talk. It will also address how to design an invasive placebo control (the DITTO framework), including deconstruction of the treatment intervention and identification of the critical surgical element Talk 3 (Marion Campbell) – The practical issues of interpretation and implementation of the new guidance This talk will address interpretation and dissemination issues, as well as presenting the ASPIRE checklist for developing a surgical placebo trial.

The final part of the session will be used to invited comments and questions from the attendees to the presenters in an open moderated discussion .

This invited session will bring together a faculty with direct experience of the design, conduct and ethical challenges posed by placebo trials in surgery. The session will involve invited talks providing an up to date review of practice and the findings from the ASPIRE guidance.

Contributors:

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