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#  PADDI wins top clinical trials award

The Perioperative Administration of Dexamethasone and Infection (PADDI) trial is the recipient of the 2022 Australian Clinical Trials Alliance (ACTA) Excellence in Trial Statistics Award.

The award was presented on International Clinical Trials Day which is held on 20 May each year to recognise the outstanding contribution of the sector in developing and leading investigator-led clinical trials.

The Excellence in Trial Statistics Award is assessed by a panel of senior statisticians who said the PADDI trial demonstrates exemplary statistical aspects from trial design and planning through to analysis reporting and interpretation. Professor Andrew Forbes, the lead trial statistician based at Monash University’s School of Public Health and Preventive Medicine, accepted the award on behalf of the PADDI investigators and the Australian and New Zealand College of Anaesthetists Clinical Trials Network (ANZCA CTN).

The PADDI trial led by Chief Investigator Professor Tomas Corcoran, Director of Research in the Department of Anaesthesia and Pain Medicine, Royal Perth Hospital and Deputy Chair of the ANZCA CTN Executive, was funded by the National Health and Medical Research Council and coordinated at the ANZCA CTN office based at Monash University.

The trial was a pragmatic randomised non-inferiority trial assessing the safety of 8mg dexamethasone versus placebo in terms of surgical site infection in 8880 patients undergoing non-urgent non-cardiac surgery across 55 centres in four countries. The trial was necessary because anaesthetists commonly administer dexamethasone to reduce the risk of postoperative nausea and vomiting during the perioperative period.

However, because dexamethasone is a glucocorticosteroid, it was feared that dexamethasone may increase infections due to the potential immunosuppressive and hyperglycaemic effects, particularly in patients with diabetes.

The results of the PADDI trial were very reassuring: the trial demonstrated conclusively that dexamethasone decreases the risk of post-operative nausea and vomiting (PONV) but does not increase the risk of overall or of subtypes of surgical site infection, including in patients with diabetes.

Clinicians may safely use it to prevent PONV without surgical site infection concerns. The results of the trial were published in the *New England Journal of Medicine* in May 2021.

Professor Forbes said: “It is an honour to receive this award on behalf of the PADDI investigators and the ANZCA Clinical Trials Network. With the expectation that PADDI would have a high impact on clinical practice, all statistical elements of the trial needed to be developed and conducted with rigour. This included the non-inferiority design, numerical simulation to validate the planned sample size, interim monitoring for non-inferiority and harm using asymmetric stopping guidelines, the final statistical analyses and interpretation of results. A detailed statistical analysis plan was developed in conjunction with the investigators and completely adhered to in the final analyses, ensuring that the methodology was pre-specified and transparent, and that the overall trial results were robust.”

**For more information or to request interviews, please contact ANZCA Media Manager Carolyn Jones on +61 3 8517 5303, +61 408 259 369 or cjones@anzca.edu.au**