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A double-blind randomized controlled trial of ibuprofen compared with placebo for uncomplicated cellulitis of the upper or lower limb

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Background: Cellulitis is a common skin and soft tissue infection resulting in substantial inflammation that may take weeks to resolve despite appropriate antibiotics. It is unclear whether the adjunctive use of non-steroidal anti-inflammatory drugs hastens the resolution of inflammation in patients with cellulitis.

Material/methods: We conducted a double-blind, parallel group randomised controlled trial comparing ibuprofen 400mg three times daily by mouth for five days with identical placebo in adults with uncomplicated cellulitis of the upper or lower limb who were treated with intravenous cefazolin via an outpatient parenteral antibiotic treatment service at one of two Australian hospitals. Participants were assessed twice daily by a study nurse. The primary outcome measure was the proportion of patients with regression of inflammation 48 hours following the first effective dose of parenteral antibiotics. This trial was registered (ANZCTR 12611000515998).

Results: Fifty-one patients were enrolled; 48 had sufficient data available to be included in the modified intention to treat analysis. Inflammation had begun to regress at 48 hours in 20 participants (80%) in the ibuprofen group compared with 15 (65%) in the placebo group (Absolute risk difference +

15% [95% CI -10% to +40%], $p>0.05$). There was also no significant difference in any of the secondary outcomes. Ibuprofen treatment appeared safe, with no patients developing renal impairment or necrotising fasciitis, and two developing transient epigastric pain which resolved without cessation of study drug.

Conclusions: This trial demonstrated no significant benefit of adjunctive ibuprofen in adults with uncomplicated cellulitis. The trial was powered to detect a large effect, and hence it is unclear if the 15% absolute increase in the primary endpoint in the ibuprofen group was attributable to chance or not.