

## **Antiseptic mouthwash for gonorrhoea prevention (OMEGA): a randomised, double-blind, parallel-group, multicentre trial**

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### **Background:**

To address the increasing incidence of gonorrhoea and concern regarding antimicrobial resistance, we compared the efficacy of Listerine™ and Biotène™ mouthwashes for preventing gonorrhoea among men who have sex with men (MSM).

**Methods:**

The OMEGA trial was a multicentre, parallel-group, double-blind randomized controlled trial among MSM conducted at four sexual health and one GP clinic in Australia. Men were eligible if they were diagnosed with oropharyngeal gonorrhoea in the last month or were aged 16-24 years. Men were randomised to the intervention (Listerine) or control (Biotène) group via a computer-generated sequence. Participants were instructed to use the mouthwash daily for 12 weeks. Oropharyngeal swabs were collected every 6 weeks and saliva samples every 3 weeks and tested for *Neisseria gonorrhoeae* with nucleic acid amplification test (NAAT). The primary outcome was detection of oropharyngeal *N. gonorrhoeae* over the 12-week period, defined as a positive result for either an oropharyngeal swab or saliva sample by NAAT. A modified intention-to-treat analysis for the primary outcome was conducted which included men who provided at least one follow-up specimen over the 12-week study period. The trial was registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12616000247471).

**Results:**

Between 31-March-2016 and 26-October-2018, 264 MSM were randomly assigned to the Biotène group, and 266 to the Listerine group. The analysis population included 227 (86.0%) men in the Biotène group and 219 (82.3%) in the Listerine group. Oropharyngeal gonorrhoea was detected in 4.4% (10/227) of MSM in the Biotène group compared with 6.8% (15/219) in the Listerine group (adjusted risk difference=2.5%; 95%CI: -1.8%-6.8%).

**Conclusion:**

Listerine did not reduce the incidence of oropharyngeal gonorrhoea compared to Biotène. Future studies should investigate different types of mouthwashes, methods of administering them, placebo preparations, and also determine if mouthwash use could potentially reduce transmission to sex partners.

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