

Male-Partner Treatment to Prevent Recurrence of Bacterial Vaginosis

A Research Summary based on Vodstrcil LA et al. | 10.1056/NEJMoa2405404 | Published on March 6, 2025

WHY WAS THE TRIAL DONE?

Studies have shown that men may harbor bacterial species associated with bacterial vaginosis in the distal urethra and subpreputial space and that the penile microbiota is predictive of a woman's risk of bacterial vaginosis. Evidence of sexual exchange of bacterial vaginosis-associated organisms suggests that treating partners could increase the likelihood of cure.

HOW WAS THE TRIAL CONDUCTED?

Women with bacterial vaginosis who were in a monogamous relationship with a male partner received first-line recommended antimicrobial agents; their male partners were assigned to receive either partner treatment — oral metronidazole and 2% clindamycin cream applied to penile skin — or no partner treatment. The primary efficacy outcome was recurrence of bacterial vaginosis within 12 weeks.

TRIAL DESIGN

- Open-label
- Randomized
- Controlled
- Location: Five health centers in three Australian states

RESULTS

The trial was stopped early after an interim analysis showed that treating only the female partner was inferior to treating both partners with respect to recurrence of bacterial vaginosis by week 12. Adverse events were reported by nearly half the treated male partners; the incidence of systemic adverse events in treated men was similar to that in the women. Common adverse events included nausea, headache, and metallic taste.

LIMITATIONS AND REMAINING QUESTIONS

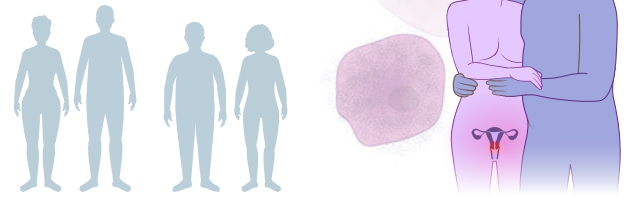
- Placebo cream was not given to any male partners, owing to concern that any topical cream might alter the penile microbiome.
- Participants and clinicians knew the trial-group assignments, but the laboratory staff and microscopist assessing the primary outcome did not.
- Most of the trial participants attended a single sexual health center in urban Australia, which may affect the generalizability of the results.

CONCLUSIONS

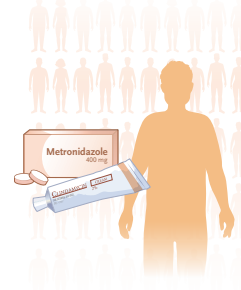
Treating male partners with oral metronidazole and topical clindamycin, in addition to treating female patients, resulted in a lower incidence of recurrent bacterial vaginosis within 12 weeks than treating only women.

Participants

- 164 adult heterosexual couples
- Women: premenopausal

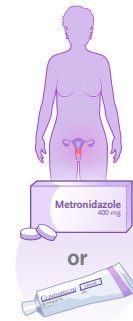


Partner Treatment



N = 81

No Partner Treatment

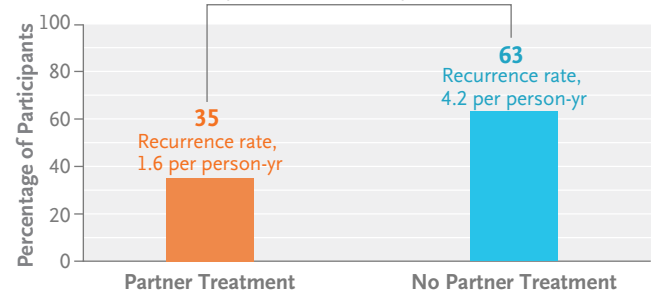


N = 83

Recurrence of Bacterial Vaginosis

Hazard ratio, 0.37 (95% CI, 0.22 to 0.61)

Between-group difference, -2.6 recurrences per person-yr (95% CI, -4.0 to -1.2); P<0.001



Adverse Events in Treated Men

