AN OPEN-LABEL RANDOMISED CONTROLLED TRIAL EVALUATING THE EFFICACY OF A MENINGOCOCCAL SEROGROUP B (4CMenB) VACCINE ON *NEISSERIA GONORRHOEAE* INFECTION IN GAY AND BISEXUAL MEN: THE MenGO STUDY

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Background:
Gonorrhoea is a public health concern with rising incidence and the emergence of antibiotic resistance. Therefore, new preventative strategies are urgently needed. Observational studies suggest that serogroup B meningococcal vaccines could provide cross-protection against *Neisseria gonorrhoeae.*

Methods:
The MenGO study is a phase III open-label randomised control trial in gay and bisexual men (GBM) to evaluate the efficacy of the four-component meningococcal serogroup B vaccine (4CMenB) against gonorrhoea. A total of 130 GBM were recruited at the Gold Coast Sexual Health Clinic and randomised (1:1) to either receive 2 doses of 4CMenB or no intervention. Participants were followed up for 24 months with three-monthly testing for *N. gonorrhoeae* and other sexually transmissible infections (STIs). The primary outcome is the number of *N. gonorrhoeae* infections determined by nucleic acid amplification test (NAAT). Secondary outcomes are vaccine-induced *N. gonorrhoeae*-specific immune responses, and adverse events in trial participants.
The trial has HREC approval (2019/QGC/48972) and is registered on the Australian and New Zealand Clinical Trials Registry (ACTRN12619001478101).
The study protocol has been published:
https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15516-y

Results:
No differences in characteristics of the 2 groups were observed. The median age of participants was 32 years (IQR 27-40). 83% were White Caucasian, 7.6% Asian, 4.6% Latino and 2.3% First Nations. 3% of participants were living with HIV infection and 65% had a past history of gonorrhoea infection. The use of pre-exposure prophylaxis for HIV use was observed in 88.5% of participants, with 66% reporting <50% condom use. In the 6 months post intervention, 62 STIs were detected of which there were 33 NG infections.
No serious adverse events related to 4CMenB vaccine have been reported to date.

Conclusion:
The study is due to complete follow up on the 29th April 2024, with a full analysis anticipated for presentation at the conference.

Disclosure of interest statement:

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