

	Sponsor	Location	Objective	Primary endpoints	Population	Study period	Study
Phase 2 mucosal immunity trial	NIAID	USA	4CMenB systemic and mucosal immunogenicity against gonorrhoea	Rectal mucosal IgG concentrations against gonococcal OMV antigens	Men and women aged 18–49 years	November, 2021–March, 2023	NCT04722003
Phase 2 RCT	NIAID	USA and Thailand	4CMenB efficacy in preventing urogenital or anorectal gonococcal infection, or both	Number of participants diagnosed with urogenital or anorectal gonococcal infection post second vaccination	Adults at risk of gonorrhoea aged 18–50 years (N=~2200)	December, 2020–September, 2023	NCT04350138
Observational, prospective cohort study (part B of it NT)	University of Adelaide	Northern Territory, Australia	4CMenB effect and efficacy against IMD and gonorrhoea	Notifications of gonorrhoea; effect of 4CMenB on carriage of all <i>N meningitidis</i>	Adolescents and young adults aged 14–19 years (N=7100)	March, 2021–December 2024	NCT04398849
Phase 3 RCT (MenGO)	Gold Coast Hospital	Queensland, Australia	4CMenB efficacy and immunogenicity against gonorrhoea	Number of gonorrhoea infections during study period; gonorrhoea-specific immune responses	MSM aged ≥18 years at risk of gonorrhoea (N=~130)	January, 2020–January, 2025	ACTRN12619001478101
Phase 3 RCT (GoGoVax)	Kirby Institute	New South Wales, Australia	Efficacy of 4CMenB in preventing gonorrhoea	Change in incidence of the first episode of gonorrhoea; comparison of incidence of gonorrhoea episodes during study period	GBM+; N=730, aged 18–40 years	July, 2021–February, 2025	NCT04415424
Phase 2 human-challenge RCT	University of North Carolina, Chapel Hill	North Carolina, USA	4CMenB efficacy against experimental urethral <i>N gonorrhoeae</i> inoculation	Infectivity of <i>N gonorrhoeae</i> inoculum between 1 day and 10 days post inoculation	Men aged 19–35 years (N=~140)	April, 2022–February, 2028	NCT05294588
Phase 3 RCT	Chinese University of Hong Kong	Hong Kong	Efficacy of 4CMenB in preventing gonorrhoea	Comparison of gonorrhoea incidence between 4CMenB and placebo groups	MSM aged 18–50 years at risk of gonorrhoea (N=~150)	May, 2023–September, 2025	NCT05766904

4CMenB=meningococcal group B vaccine. GBM+=gay bisexual men+ (men [cis and trans], trans women and non-binary people who have sex with men). IMD=invasive meningococcal disease. MSM=men who have sex with men. *N gonorrhoeae*=Neisseria gonorrhoeae. NIAID=National Institute of Allergy and Infectious Diseases. *N meningitidis*=Neisseria meningitidis. NT=Northern Territories. OMV=outer membrane vesicle. RCT=randomised controlled trial.

Table 2: Ongoing studies with 4CMenB and gonorrhoea