

Project Brief: BIYELA

Title	A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Assess Efficacy of Meningococcal Serogroup B Vaccine rMenB+OMV NZ (Bexsero) in Preventing Gonococcal Infection Among Individuals Born Female in South Africa. Short title: Bexsero Immunisation In Young Women in Africa (BIYELA)
Focus area	Gonorrhoea prevention
Primary objectives	To assess efficacy of Bexsero in prevention of cervical and/or anorectal gonococcal infection.
Primary endpoint	First diagnosis of gonorrhoea at cervical or anorectal sites occurring > 1 month after the second vaccination with study product through to study end
Study design	1:1 randomization to Bexsero vaccine or placebo injection, to be administered as two intramuscular (IM) doses, two months apart (at Enrolment/Visit 1 and Month 2/Visit 3). Assessment for safety events at one month following the IM doses (Visit 2 and Visit 4), followed by 5 in-clinic follow-up visits for safety, clinical, and laboratory assessments.
Study population	Approximately 1100 healthy individuals born female, 18-45 years of age, of whom approximately 200 will be living with HIV and 900 will be HIV uninfected. All individuals will be at risk for gonorrhoea. Participants will be enrolled at 5 sites across South Africa: 1 site in Johannesburg (Wits RHI Ward 21 Clinical Research Site), 1 site in Pietermaritzburg, and 3 sites in Cape Town.
Intervention	Bexsero (rMenB+OMV NZ) is a four-component meningococcal serogroup B vaccine administered intramuscularly (IM) as two 0.5 mL doses, given two months apart (at Enrolment/Visit 1 and Month 2/Visit 3). The placebo, 0.5 mL of sterile sodium chloride (saline), is also administered IM on the same schedule. Participants are randomized 1:1 to receive either Bexsero or placebo. Both participants and study staff are blinded to the product administered. This intervention aims to evaluate Bexsero's efficacy in preventing gonococcal infections in women in South Africa.
Study duration	Participation will include a Screening Visit, an Enrolment Visit at day 1 (Visit 1) with randomization and initial vaccine or placebo dose, a post-vaccination assessment at month 1 (Visit 2), a second vaccine or placebo dose at month 2 (Visit 3), a post-vaccination assessment at month 3 (Visit 4), and 5 quarterly clinical follow-up visits (Visits 5 to 9) up to 18 months (i.e., 16 months after the second dose). Total study duration for participants will be up to 18 months to allow for assessment of durability of protection.
Sponsors/donors	Bill and Melinda Gates Foundation, University of Washington
Study status	Enrolment was completed on 08 April 2025. This study is currently in the follow-up stage. The last participant last visit is expected to occur in October 2026.
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