

Treponemal Shedding, Load, and Viability, in Women and Men-who-have-sex-with-women-only With Early Infectious Syphilis: Implications for Transmission

NCT07300254

Status	RECRUITING
Sponsor	Monash University
Enrollment	480 participants

Key Eligibility Criteria

Inclusion (7)

- \- 1. Any cis-woman, cis-MSW, or nonbinary individuals with a penis who have sex with women only, (who meet all other study criteria) 2. Aged e18 years of age, 3. At least one sexual partner in the last 12 months 4. One of either:
 - a. Untreated clinically suspected primary or secondary syphilis. i. Must have rash or lesion(s) clinically suggestive of early infectious syphilis infection.
 - ii. May have positive PCR result, positive Dark-ground Microscopy result, positive syphilis serology or positive point-of-care syphilis test, but these are not necessary at the time of enrolment.
 - b. Untreated early latent (no clinical signs indicative of primary or secondary syphilis) syphilis with positive syphilis serology or positive point-of-care test, and one or more of the following(11): i. A documented syphilis seroconversion within the prior 12 months. ii. A sustained (longer than 2 weeks) fourfold or greater increase in the titre in the prior 12 months in a person previously treated for syphilis.
 - iii. Unequivocal symptoms of primary or secondary syphilis within the prior 12 months.
- ... and 2 more (see full listing online)

Exclusion (3)

- Men, transwomen, or other people, with a penis, who have had any sexual contact, including kissing, oral sex or anal sex, with men (or any other individual with a penis) in the previous one year.
- Individuals who have received antibiotic treatment within 1 month prior to enrolment, with the EXCEPTION of metronidazole.
- Diagnosis of late latent syphilis (>1 year) or latent syphilis of unknown duration.

Locations (9 total)

Monash University, Melbourne, Victoria, Australia
Xinhua Hospital Affiliated to Shanghai Jiaotong University School of Medicine, Shanghai, Shanghai Municipality, China
Shanghai Skin Disease Hospital, Shanghai, Shanghai Municipality, China
... and 6 more locations

<https://clinicaltrials.gov/study/NCT07300254>

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