

Study to Evaluate the Potential Effects of KH-001 on Intravaginal Ejaculatory Latency Time (IELT), Patient-Reported Outcomes, and Safety in Men With Lifelong Premature Ejaculation (LPE)

NCT07434271

Status	RECRUITING
Phase	Phase 2
Sponsor	Kadence Bio
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (13)

- Male participants aged 18 to 65 years (inclusive) at the time of informed consent.
 - In a stable (e6 months) monogamous heterosexual relationship.
 - Self-reported lifelong premature ejaculation (LPE), meeting the ISSM definition.
 - Intravaginal Ejaculatory Latency Time (IELT) d1 minute on at least 75% of intercourse attempts during the 4-week run-in period.
 - PEDT (Premature Ejaculation Diagnostic Tool) score e11.
- ... and 8 more (see full listing online)

Exclusion (17)

- IELT \>1 minute on more than 25% of attempts during the run-in period.
 - Fewer than 4 intercourse attempts during the run-in period.
 - Self-rated control of ejaculation as fair, good, or very good on the PEP.
 - Low personal distress ("not at all" or "a little bit") on the PEP.
 - Erectile dysfunction (IIEF Questions 1-5 sum score \<21).
- ... and 12 more (see full listing online)

Locations (1 total)

Emeritus Research Sydney, Botany, New South Wales, Australia