Proof of Concept Study on BP1.4979 Effect on Primary Premature Ejaculation

NCT07047404

Status	RECRUITING
Phase	Phase 2
Sponsor	Bioprojet
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (6)

- Males aged 18 to 50 years old (both inclusive)
- Diagnosis of primary (lifelong) PE according to the investigator
- Intravaginal Ejaculatory Latency Time (IELT) estimated by the patient around one (1) minute at screening
- Confirmation at randomization visit that at least 3 timed sexual intercourses with each IELT below 90 seconds occurred during the baseline period
- Patient must be able to provide an informed consent and voluntarily express a willingness to participate in this study, and must sign and date an informed consent prior to any study specific procedure

... and 1 more (see full listing online)

Exclusion (5)

- Diagnosis of acquired PE, pseudo-PE or natural variable PE
- History of clinically significant abnormalities comprising cardiovascular (including especially prolonged QTc (\>450 ms) and high degree (second and third) atrio-ventricular blocks)), hematological, neurological, and endocrine diseases
- Current therapy with any treatment which may impact PE from 4 weeks prior to the screening visit
- Current therapy with any treatment displaying dopamine D3 receptor agonist properties from 4 weeks prior to the screening visit
- Concomitant intake of psychoactive / chem-sex substances

Locations (1 total)

University Hospital of Nîmes, Nîmes, France