A Study to Test How BI 3031185 is Tolerated by People With Borderline Personality Disorder or Attention-deficit/Hyperactivity Disorder

NCT07001475

Status	RECRUITING
Phase	Phase 1
Sponsor	Boehringer Ingelheim
Enrollment	96 participants

Key Eligibility Criteria

Inclusion (3)

- Male, female, and non-binary participants, 18 to 45 years of age, both inclusively, at the time of consent
- Meet current Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) criteria as primary diagnosis as assessed by the Mini International Neuropsychiatric Interview (MINI) at screening for borderline personality disorder (BPD) OR attention-deficit/hyperactivity disorder (ADHD)
- Willingness to abstain from alcohol for 24 h, and all other drugs of abuse including cannabis for 72 h prior to Visits 2 and 3 (Day -1). Willingness to abstain from alcohol and cannabis for 72 h after investigational medicinal product (IMP) administration, as well as from all other recreational drugs for the duration of the trial

Exclusion (11)

- Lifetime diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, bipolar I disorder, delusional disorder, autism spectrum disorder, or antisocial personality disorder as confirmed by the MINI
- Any other psychiatric disorder that is not currently stable in symptoms and treatment
- Any substance use disorder within 3 months prior to randomisation (excluding mild alcohol, cannabis, tobacco, and caffeine use disorders); or moderate to severe substance use disorder within the 6 months prior to randomisation (excluding tobacco and caffeine)
- Positive drug screen. Participants with positive cannabis drug tests can be included if they do not meet criteria for moderate or severe cannabis use disorder and the investigator determines that use will not be an impediment to trial participation or accurate data collection
- Concomitant use of psychotropic medication except for the ones below. All other psychotropic medications must be washed out at least 30 days or 5 Half-life time (t1/2) (whichever is longer) before the start of Visit 2 (Day -1)

... and 6 more (see full listing online)

Locations (7 total)

Charité Research Organisation GmbH, Berlin, Germany
Universitätsklinikum Bonn AöR, Bonn, Germany
Universitätsklinikum Frankfurt, Frankfurt am Main, Germany
... and 4 more locations