A Study to Test Whether BI 1356225 Improves Impulsive Behavior in Men With Opioid Use Disorder Who Are Taking Buprenorphine

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 65 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Male participants, 18 to 65 years of age, both inclusively, at the time of consent 2. Meet current diagnostic and statistical manual of mental disorders, fifth edition (DSM-5) criteria for opioid use disorder, of at least moderate severity within the 12 months prior to screening 3. Currently engaged in medications for opioid use disorder (MOUD) treatment with one of the following regimens: 1. buprenorphine/naloxone sublingual film total daily dose ranging from 8 mg/2 mg to 24 mg/6 mg for at least 2 weeks at screening OR 2. buprenorphine/naloxone sublingual tablet from 5.7 mg/1.4 mg to 17.1 mg/4.3 mg total daily dose for at least 2 weeks at screening OR 3. buprenorphine sublingual tablet from 8 mg to 24 mg total daily dose for at least 2 weeks at screening OR 4. on a stable dose of depot injectable buprenorphine for at leas 5 weeks at screening, with at least 1 week since last depot buprenorphine injection 4. Have a current MOUD prescription in accordance with inclusion criterion 4 and a positive urine drug screen for buprenorphine during screening and upon presenting for randomization to document buprenorphine use 5. Willingness to abstain from using alcohol for 24 hours (h) and all other drugs of abuse for 72 h prior to Day 1 and through discharge from the trial site on Day 9 6. Further inclusion criteria apply

---

Exclusion Criteria:

1. Lifetime diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, bipolar I disorder, delusional disorder, or autism spectrum disorder as confirmed by the mini international neuropsychiatric interview (MINI) at the screening visit 2. Moderate or severe substance use disorder other than opioid use disorder (OUD) within the 6 months prior to screening (excluding tobacco, caffeine, and moderate stimulant use) 3. Severe stimulant use disorder within the 6 months prior to screening 4. Any other psychiatric disorder that is not currently stable in symptoms and treatment. Stable is defined as having no significant changes in symptom acuity or treatment (medication or psychotherapy treatment) in the 8 weeks prior to randomization 5. Score of ≥20 on the Montgomery-Åsberg Depression Rating Scale (MADRS) 6. Positive results on a urine drug screen for ≥3 drugs (not counting buprenorphine or TCAs) at screening. In the case of a positive drug screen for 1 or 2 agents, if the participant does not meet the exclusion criteria regarding substance use disorder for these compounds, they may be included if the investigator determines that use will not be an impediment to trial participation or accurate data collection 7. Any positive result on a urine drug screen (not counting buprenorphine, TCAs, or cannabis) at admission to the trial site on Day -1 8. Intoxication at screening or randomization, as determined by clinical exam and breathalyzer 9. Further exclusion criteria apply

Conditions & Interventions

Interventions:
DRUG: BI 1356225, DRUG: Placebo
Conditions:
Opioid Use Disorder

More Information

Contact(s): Boehringer Ingelheim - clintriage.rdg@boehringer-ingelheim.com
Principal Investigator:
Phase: PHASE1
IRB
Number:
System ID: NCT06628622
