Effects of Lemborexant on Insomnia and Its Relationship to Mood and Behavior on Opioid Use Disorder Subjects

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Be 18 + years-of-age 2. Meet current DSM-5 criteria for opioid use disorder (OUD) with at least moderate severity 3. Receiving outpatient treatment for OUD with sublingual buprenorphine film/tablets ranging 8mg to 24mg or with extended-release injectable buprenorphine 4. Stabilized on current buprenorphine dosage for at least 4 weeks without intention for dose change within next 3 months. 5. Screening urine toxicology positive for buprenorphine and an appropriate norbuprenorphine level as determined by a study clinician 6. A screening urine toxicology negative for non-prescribed substances (except cannabinoids) with a negative breath (or oral fluid) alcohol screen 7. Screen positive for chronic insomnia on the Insomnia Symptom Questionnaire (ISQ) 8. Have an Insomnia Severity Index score at screening and baseline of 13 or higher 9. Have no clinically significant medical or psychiatric disorder or condition, based on physical exam and medical history performed by study clinician, that in the judgement of the investigator would prevent participation or heighten safety risks 10. Understand the study procedures and provide written informed consent in English language 11. Access to necessary resources for completing virtual surveys and monitoring (i.e., computer or smartphone, internet or cell service)

Exclusion Criteria:

1. Current diagnosis of sleep-related breathing disorder, narcolepsy, somnambulism, or sleep paralysis 2. A positive screen for sleep apnea by the following: Sleep Disorders Screening Battery (STOP-BAG \>5) OR home sleep apnea test using WatchPAT with Apnea Hypopnea Index (AHI) with 3% drop in oxygen saturation \> 10 OR \>50% of respiratory events being central if AHI is between 5-10 OR Oxygen Desaturation \< 88% for \> 10 minutes, OR oxygen desaturation index (ODI) using 3% drop in oxygen saturation \> 10 3. Currently receiving treatment for insomnia (behavioral or pharmacologic) 4. Currently taking a medication to treat a sleep-related condition (e.g., zolpidem) or unable to discontinue over-the-counter drug or supplement used to treat sleep-related condition 5. Currently taking benzodiazepines or other CNS active medications that may increase risk to the participant, per PI discretion (e.g., opioids other than buprenorphine, antipsychotics) 6. Current DSM-5 diagnosis (any severity) of alcohol or drug use disorder (e.g., benzodiazepine, stimulant) with non-prescribed substance use within last 3 months; nicotine use disorder is not considered exclusionary 7. Cannabis use \> 3 days/week 8. Uncontrolled serious psychiatric disorder that would make study participation unsafe (such as Bipolar I Disorder, ADHD, Schizophrenia, schizoaffective disorders, major depressive disorder with psychotic features, or a neurological disorder). 9. Uncontrolled neurological, cardiovascular, or pulmonary medical condition such as seizure disorder, recent myocardial infarction, stroke, hospitalization for chronic obstructive pulmonary disease 10. Baseline ECG with clinically significant abnormal conduction or with QTc of greater than 450ms 11. Significant current suicidal or homicidal ideation (C-SSRS "yes" answers on questions 4 or 5) or a history of suicide attempt within the past 6 months 12. Any of the following lab abnormalities: ALT/AST 2 or more times the upper limit of normal, Total bilirubin 2 or more times the upper limit of normal, Creatinine 1.5 or more times the upper limit of normal 13. Pregnant or breastfeeding; Females who are having sex that includes penile penetration must be non-pregnant, non-lactating, and either be of non-childbearing potential (e.g., sterilized via hysterectomy, bilateral tubal ligation, or bilateral oophorectomy, or at least 1 year post-menopausal) or of childbearing potential, and agree to use an acceptable form of contraception (e.g., IUD, hormonal implant, hormonal patch/ring/pill, condoms (male or female), etc.) 14. Currently taking prescription or over-the counter drugs or dietary supplements known to significantly inhibit CYP3A4 (such as clarithromycin, telithromycin, nefazodone, itraconazole, ketoconazole, atazanavir, darunavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir); or CYP3A4 inducers (such as phenobarbital, phenytoin, rifampicin, St. John's Wort, and glucocorticoids) 15. Currently taking lemborexant or any previous medically adverse reaction to lemborexant or other dual orexin receptor antagonists 16. Currently incarcerated or pending incarceration

Conditions & Interventions

Interventions:
DRUG: Placebo, DRUG: Lemborexant 10 MG
Conditions:
Opioid Use Disorder, Opioid Use, Insomnia, Orexin Antagonist
Keywords:
buprenorphine, lemborexant

More Information

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