A Study of Suvorexant (MK-4305) for the Treatment of Insomnia Disorder in Participants With Opioid Use Disorder (MK-4305-098)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 70 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

The main inclusion criteria include but are not limited to the following: * Has a primary diagnosis of OUD according to Diagnostic and Statistical Manual of Mental Disorder, 5th Edition (DSM-5), and confirmed through the Mini International Neuropsychiatric Interview (MINI). * Is on a verified, stable dose of medications for opioid use disorder (MOUD) treatment. * Meets DSM-5 criteria for the diagnosis of Insomnia Disorder * Has a regular bedtime between 8 PM (20:00) and 1 AM (01:00) and is willing to maintain it for the duration of the study. * Has not used opioids for a period of at least 4 weeks before entering the study.

Exclusion Criteria:

The main exclusion criteria include but are not limited to the following: * Has current uncontrolled major co-morbid psychiatric illness including major depressive disorder, bipolar disorder, schizophrenia, or any psychiatric condition with psychotic features. * Has current diagnosis or history within 5 years of any of the following: narcolepsy, sleep paralysis, severe periodic limb movement disorder, restless leg syndrome, cataplexy, circadian rhythm sleep disorder, parasomnia including nightmare disorder, sleep terror disorder, sleepwalking disorder, rapid eye movement (REM) behavior disorder, significant degree of sleep-related breathing disorder, excessive daytime sleepiness (EDS), or primary hypersomnia. * Is at imminent risk of self-harm. * Has a known history of stroke that may confound the diagnosis of insomnia. * Has a clinically significant movement disorder such as akinesia. * Has a history of hepatitis or live disease. * Has habitual use of central nervous system (CNS)-depressants or stimulants that may be responsible for the participant's disturbed sleep. * Has a history of malignancy, ≤3 years prior to start of study, with the exception of nonmelanoma skin cancer, prostate cancer or localized carcinoma in situ of the cervix. * Has a history of hypersensitivity to more than 3 chemical classes of drugs, including prescription and over-the-counter medications. * Has donated blood products or had phlebotomy within 8 weeks prior to start of study. * Has a history of transmeridian travel within 2 weeks prior to start of study.

Conditions & Interventions

Interventions:
DRUG: Suvorexant, DRUG: Placebo
Conditions:
Insomnia

More Information

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IRB
Number:
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