NIDA CTN PROTOCOL 0102-XR

Rural Expansion of Medication Treatment for Opioid Use Disorder

Randomized Controlled Pilot Trial of Extended-release Buprenorphine (XR-BUP) vs. Sublingual Buprenorphine-naloxone (SL-BUP) in Rural Settings

STUDY OVERVIEW

Study Synopsis

This 2-year pilot study will explore the feasibility, acceptability, and effectiveness of the most recent formulation of injectable extended-release buprenorphine (XR-BUP) for treatment of opioid use disorder (OUD) in rural settings, as compared to sublingual buprenorphine-naloxone (SL-BUP). A total of 6 rural clinic sites will be selected for this trial. It is expected that each participating site will enroll 24 patients into the study over a 6-month recruitment period. Eligible, consenting individuals will be randomized within sites 2:1 to either XR-BUP or SL-BUP for a 14-week intervention, with a total of 96 participants randomized to XR-BUP and 48 participants to SL-BUP across all sites. Participants in both arms will receive Medical Management; any additional patient care services (e.g., psychosocial therapy, counseling) will be delivered per usual care as practiced at individual sites. The main comparative effectiveness outcome will be the number of urine drug screen (UDS) results that are negative for opioids at scheduled assessments during Week 2 through Week 14 of the trial, which can be expressed as the percentage of UDS across the last 12 weeks of the trial that are negative for opioids.

Participant Inclusion Criteria

To be eligible for participation, candidate individuals ***must*:**

1. Be ≥18 years of age;
2. Meet DSM-5 criteria for moderate to severe OUD or be on buprenorphine medication for OUD;
3. Be interested in receiving buprenorphine treatment for OUD;
4. Be willing to be randomized to either SL-BUP or XR-BUP and to comply with study procedures;
5. Be in good general health as determined by the Study Medical Clinician on the basis of medical/psychiatric histories and physical exam to permit treatment in an outpatient setting;
6. If female of childbearing potential, be willing to practice an effective method of birth control for the duration of participation in the study intervention and agree to study-administered pregnancy testing during their participation in the study;
7. Be able to speak English sufficiently to understand the study procedures; and
8. Be willing and able to and provide written informed consent to participate in the study.

Participant Exclusion Criteria

To be eligible for participation, candidate individuals ***must not***:

1. Have evidence of a serious psychiatric disorder as assessed by the Study Medical Clinician that would make participation difficult or unsafe (e.g. active psychosis, severe depression, or mania);
2. Have suicidal or homicidal ideation that requires immediate attention;
3. Have a serious medical illness that, in the opinion of the Study Medical Clinician, would make study participation medically unsafe;
4. Have been in treatment with naltrexone within 28 days of consent;
5. Have been in methadone maintenance treatment within 28 days of consent;
6. Be taking medication or require any medication that, in the judgment of the Study Medical Clinician, could interact adversely with study medication;
7. Have known allergy or sensitivity to SL-BUP or XR-BUP formulations or their components;
8. Be currently incarcerated or have pending legal action that could preclude participation in study activities;
9. Have other situation that might prevent remaining in the area for the duration of the study (e.g. planned move, planned surgery);
10. Have a current pattern of alcohol, benzodiazepine, or other sedative hypnotic use, as determined by the Study Medical Clinician, that would require a different level of care and preclude safe participation in the study; and
11. Be currently pregnant or breastfeeding or planning on conception.

Site Eligibility: The CTN-0102-XR trial will be conducted in approximately 6 healthcare settings serving rural communities that meet the following criteria:

1. Treat large numbers of patients with opioid use disorder (OUD) with SL-BUP (e.g., 200 or more); sites that also have some experience with XR-BUP are preferred;
2. Be willing to participate in research in which patients are randomized to SL-BUP or XR-BUP(including patients initiating MOUD, or already taking SL-BUP);
3. Have the capacity to maintain participants on SL-BUP and XR-BUP for the duration of the study;
4. Have sufficient flow/volume of patients to be able to randomize at least 4 participants per month;
5. Be willing to engage in community outreach to bring new patients with OUD into their clinics if necessary to meet recruitment goals; and
6. Have on staff a licensed waivered physician/medical clinician (e.g., NP, PA) capable of completing all medical assessments, administering medical interventions, and providing medical treatment.

Potential Benefits of Site Participation Include:

1. Funding for study-related staff (e.g., Site Principal Investigator, Study Medical Clinician, and Research Associate);

2. NIDA (via CCC) will provide study medications (XR-BUP, SL-BUP). All ancillary medications (e.g., for opioid withdrawal symptoms, sleeplessness, depression, or other psychiatric or medical conditions) must be provided by the site;
3. Opportunity to participate in an important national study to improve access to MOUD for patients with OUD in rural communities; and
4. Opportunity for community outreach and to expand services to more individuals in need.