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# NIDA-CTN-0002

## *Buprenorphine/Naloxone versus Clonidine For OUTpatient Opiate Detoxification*

STUDY OBJECTIVES:

To assess the relative clinical utility of buprenorphine-naloxone (BUP/NX) in comparison to clonidine for short term opiate detoxification in the outpatient setting. It is hypothesized that BUP/NX detoxification will be more effective in sustaining treatment retention and abstinence, reducing the amount of ancillary medications used, and alleviating withdrawal symptoms than clonidine detoxification.

STUDY DESIGN:

This is a randomized, open-label, parallel-group design study in which, after screening and baseline assessments are performed, patients will be randomly assigned in a 2:1 ratio to either a BUP/NX or clonidine 14 day detoxification regimen, respectively. The standard counseling procedures used at each clinic, along with self help detoxification handbooks, will be offered to all patients on the study. After the 14-day detoxification period, patients will be assessed for relapse, withdrawal symptoms, and treatment satisfaction at follow-up visits occurring 1, 3 and 6 months after starting detoxification.

STUDY POPULATION:

Three hundred sixty (360) patients with Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (DSM-IV) criteria for opiate abuse or dependence determined by structured clinical interview (SCID) will be randomized into one of two treatment groups (240 in the BUP/NX group and 120 in the clonidine group).

ELIGIBILITY CRITERIA:

Treatment seeking males and females, at least15 years-of-age, with a DSM-IV diagnosis of opiate abuse or dependence with the ability to understand and provide written informed consent will be included. Women of childbearing capacity will be required to use an acceptable method of birth control.

Patients will be excluded if they have any medical condition that would make participation medically hazardous, have known allergy or sensitivity to buprenorphine, naloxone, or clonidine, or have acute psychosis, severe depression, or immediate suicide risk. Patients who are dependent upon alcohol, benzodiazepines, or other depressants or stimulants, requiring immediate medical attention or who have participated in another investigational study within the last 30 days will be excluded. Patients who have had methadone or LAAM maintenance or detoxification within 30 days of

enrollment will also be excluded. Patients who have pending legal actions or for any reason are unable to remain in the area for the duration of treatment will be excluded.

STUDY INTERVENTIONS:

Patients randomized to the BUP/NX arm will receive daily doses for 14 days with sublingual administration of 2 mg buprenorphine – 0.5 mg naloxone tablet(s) and/or an 8 mg buprenorphine – 2.0 mg naloxone tablet(s). The starting dose on day 1 is 4 mg/1 mg BUP/NX with an additional 4 mg/1 mg, if needed, escalating in a step-wise manner to 16 mg/4 mg BUP/NX on day 3 and tapering to 2 mg/ 0.5 mg BUP/NX by days 12 to14. Patients randomized to the clonidine arm will receive oral clonidine (0.05 to 0.1 mg depending upon weight) every 4 to 6 hours for 24 hours not to exceed 0.6 mg total on day 1. On day 2, a clonidine transdermal patch will be applied (0.1 mg/day/7-day patch with number of patches adjusted by weight). Oral clonidine will continue to be given on the second day of detoxification and increased to 0.2 mg every 6 hours or 0.1 mg every 3 hours not to exceed 0.8 mg over 24 hours. Patches will be worn all 14 days of detoxification. The dose of clonidine will be adjusted according to the proposed detoxification schedule, patient's weight, tolerance, and systolic blood pressure. Patients will receive counseling according to procedures in existence at each CTP throughout the study. Self-help detoxification handbooks will be distributed to all study participants.

DURATION OF THE STUDY:

The total duration of study participation for each patient will be a maximum of 6 months consisting of: screening and baselineassessments; detoxification (14 days); and, follow-up evaluations conducted at 1, 3 and 6 months after enrollment. It is estimated that 2 patients will be enrolled per site per week with a total of 6 sites. Thus, the estimated length of enrollment is 30 weeks.

SAFETY ASSESSMENTS:

Before any study procedures are performed, patients will be required to provide signed informed consent. All candidates for study enrollment will have a physical examination including vital signs and weight, medical history and history of prior medication use assessment, and psychiatric evaluation including a checklist for opiate dependence from the structured clinical interview (SCID), a Brief Symptom Inventory (BSI), HIV risk assessment, and clinical laboratory studies (blood chemistry, hematology, Hepatitis B and C serology, and urinalysis) performed during screening/ baseline. All patients will have a 12-lead electrocardiograph (ECG). Females will be given a pregnancy test. Assessments of adverse events (AEs) and concomitant medication use will be performed daily during detoxification and at the one-month visit.

OUTCOME ASSESSMENTS:

Abstinence from opiates, amphetamines, cocaine, cannabinoids, and benzodiazepines will be assessed by urine drug screen measured at baseline, throughout detoxification, and at follow-up. Treatment retention will be calculated as the number of days each patient received his/her detoxification medication. The patient's status in the study will be tracked with a Treatment Status Survey (TSS). The amount of ancillary medications will be calculated by dose administered and adjusted according to symptomology (i.e., several medications are permitted for treating anxiety, insomnia, nausea, etc.) during detoxification. Withdrawal symptoms will be assessed using the clinical opiate withdrawal scale (COWS), the adjective rating scale for withdrawal (ARSW), and visual analog scales (VAS) during detoxification and at follow-up (COWS and

ARSW only). Additional measures of overall treatment effect will include a shortened version of the Addiction Severity Index (ASI), a client satisfaction questionnaire (CSQ), and SF-36 Health-related Quality of Life questionnaire administered at all follow-ups.

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