

FAQ (CONTINUED)

4. Is the information I provide confidential?

We will do everything possible to protect your privacy, including but not limited to:

- Marking the information you provide with only a number, not your name.
- Storing all research materials in a locked cabinet.
- Ensuring that only authorized research staff can access computerized data.

5. What if I decide to drop out?

This study is entirely voluntary. You can withdraw at any time.

6. What happens at the end of the study?

At the end of your participation, if you feel you need further treatment, your physician will explain your options and provide a list of local referrals.

FOR MORE INFORMATION

For more information on the National Institute on Drug Abuse Clinical Trials Network, visit the NIDA web site at "<http://www.drugabuse.gov>".

For information on other clinical trials, the National Institutes of Health has created a web site to help patients, family members, and the general public can obtain information about government sponsored clinical trials. You may log on to "<http://www.clinicaltrials.gov>" to learn about ongoing or new trials of all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The web site is maintained and updated regularly by the National Library of Medicine.

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NIDA NATIONAL INSTITUTE
ON DRUG ABUSE

*National Drug Abuse Treatment
Clinical Trials Network*



Should I Participate?

**Prescription
Opioid
Addiction
Treatment Study**

INTRODUCTION

Do you think you may be dependent on prescription opiates? Seeking treatment can be your first step to recovery from a dependence on opiates.

In October 2002, the FDA approved a drug called buprenorphine naloxone (BUP/NX) as an alternative to methadone treatment.

This study is designed to help providers determine the best way to use BUP/NX with their patients who have become addicted to prescription opiates.

WHO CAN PARTICIPATE?

Participation is always completely voluntary; you can stop any time you want. You may be eligible for the study:

- Are at least 18 years old;
- Are dependent on opiates;
- Want to be treated with a medication therapy; and
- Are not allergic to the study medications and do not have another problem that would make participation dangerous.

About the Study

In this study, you will receive at a minimum:

- A medication that can help control your cravings and withdrawal symptoms;
- Medical supervision; and
- Guidance for further support.

Phase 1 treatment lasts four weeks. If you need and desire more treatment, you may have the opportunity to enter Phase 2 treatment, which lasts four months.

Participants for both phases are followed up for two months, after being tapered off BUP/NX.

In both phases, all participants will receive medical counseling. Some participants will also receive additional individual drug counseling.

You will also be encouraged, (but not required) to attend support groups such as Narcotics Anonymous, Alcoholics Anonymous, or Smart Recovery.

FAQ

1. How long will I be in the study?

Participation lasts between 3 and 9 months; including follow-up after your treatment ends. The total time depends on which phases you enter.

2. What are the benefits of participating?

BUP/NX may help you stop using opiates by reducing withdrawal and cravings. Counseling may help you to deal with your urges to use drugs and other problems.

In addition, you will be compensated for your time in the study.

3. What risks am I taking by participating in the study?

There are some risks to taking any medication, and BUP/NX is no different. The researchers will review known risks and side effects with you before you decide to participate. You will also be monitored for any side effects while you are in the study.

Still, some side effects may be unknown. This medication may interact with other prescription or over-the-counter medications or illegal drugs or alcohol to produce side effects. You should ask the medical clinician before taking any medication.