

Questions About the Study

5. What will happen if I become pregnant while in the study?

If you become pregnant during the study, your study doctor will discuss your choices with you. Your choices will depend on when you became pregnant during the study. In any case, your doctor will want to know what happens to you during your pregnancy and when your baby is born.

6. What happens at study follow-up visits?

Study follow-up visits include:

- * Questions about your health and how you are feeling
- * Questions about drugs or other medications you are taking
- * Questions about how you are doing in different areas of your life (for example, family/social, legal, employment areas)
- * Providing a urine sample

The study follow-up visits will take about one hour each to finish.

7. What will I get for taking part in the study?

The medications used in this study may help with your withdrawal symptoms during detoxification. You will get additional monitoring of your symptoms during the study, which might not be available to you otherwise. Finally, you will receive up to \$125 worth in cash or goods for doing the screening/baseline and all follow-up interviews.

8. Will I have any bad effects from taking part in the study?

The medications used in this study have many possible side effects. During your participation in this study, you will be watched for known side effects of the medications you will be taking. Still,

some side effects may be harmful, some may be unknown. The study medications may conflict with other prescription or over-the-counter medications, or interact with illegal drugs or alcohol to produce side effects. Therefore, you should ask your doctor before taking any medication.

You should know the possible side effects of a medication before you decide to take it. Your informed consent paper will list the side effects for each of the medications you will take.

Also, much of the information collected during the study is sensitive and there is a risk that others who are not involved in the study will see it. However, this is a relatively small risk since the investigators and staff are well-trained in keeping the information confidential. Your name will not appear on any of the information you give us. Instead, you will be assigned an ID number that will be used on all forms. In addition, all information collected from study volunteers will be kept in locked areas in this clinic.

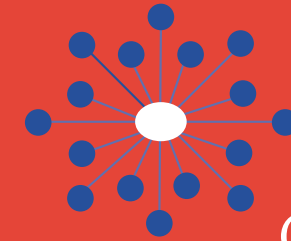
For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at www.nida.nih.gov or www.drugabuse.gov

For information on other clinical trials, the National Institutes of Health (NIH) has created a website to help patients, family members, and the general public obtain information about government sponsored clinical trials. You may log on to www.Clinicaltrials.gov to learn about ongoing or new trials for 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 website is maintained and updated regularly by the National Library of Medicine.

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National Drug Abuse Treatment

Clinical Trials Network



Bup/Nx
and
Clonidine

A MEDICATION
COMPARISON STUDY

Should I join?

*Forging partnerships to
improve the quality of
drug abuse treatment
throughout the nation...*

NIDA NATIONAL INSTITUTE
ON DRUG ABUSE



Introduction

Doctors still do not know which medication is best for detoxifying heroin addicts. The National Drug Abuse Treatment Clinical Trials Network (CTN) is doing a study called *BUP/NX versus Clonidine for Opiate Detoxification: A medication comparison study* to find out which of two medications may be better for patients who are entering opioid detoxification.

The purpose of this study is to test two different medications to treat opiate withdrawal during detoxification. Both medications will be provided free of charge.

The medications that will be tested are:

1. *Clonidine* – commonly used to treat symptoms of opiate withdrawal; it comes in a pill that you will take at the beginning of the study and then a "patch" that you wear during treatment. You may or may not continue taking the pills.
2. *BUP/NX* – is a combination of buprenorphine and naloxone. Buprenorphine is an analgesic that is being investigated as an alternative to methadone treatment. Naloxone is an opioid antagonist used to prevent opiate overdose. The combination comes in a pill that you hold under your tongue until it dissolves.

There are many other types of treatment for opioid dependence available to you. You are being asked to take part in this study to help find the best medication for people like yourself who want to detoxify from opioids.

You may choose not to take part in the study. If you choose not to take part, your treatment will not be affected in any way and you will not lose any of the treatment services you would normally receive at this clinic.

If you are interested in taking part in the study, an intake counselor or study coordinator will need to get your written permission before joining. You will need to understand and sign an informed consent paper. You may ask as many questions as you want to help you decide whether or not to join. Also, your doctor, nurses and research assistants will interview you to determine if you are qualified to participate in the study. This is called the screening/baseline phase. You will be paid \$25 for completing this phase. This phase includes:

- * Blood and urine tests
- * A pregnancy test if you are a woman able to have children
- * A physical exam
- * Questions about your health and how you are feeling
- * Questions about your drug use
- * Questions about your previous drug treatments

If you take part in the study, here is what you can expect:

1. You will be assigned at random to receive one of the medications for detoxification (that means you will not have the choice of which medication you will get). Two out of three people will be assigned to get BUP/NX, therefore you are twice as likely to get assigned to the BUP/NX than the clonidine group. If you decide to take part in this study you must be willing to take either of the medicines you may be assigned.
2. Your doctor will discuss with you the medication that you will be receiving and give you instructions on how to take it.
3. Your doctor will follow you closely while you are on the medication. You may be given other medications for treating symptoms that come up while you are detoxifying from opiates (for example, for nausea, diarrhea, or sleeplessness).

4. You will often meet with a research assistant as well as study doctors and nurses. The research assistant will collect important information from you, help you fill out questionnaires, collect urine samples, contact you for follow-up visits, and help with answering any of the questions you might have.
5. You will need to give a urine sample several times during the study. These will be tested for opiates, methadone, cocaine, amphetamines, marijuana, and benzodiazepines.
6. You will need to return to the clinic 1, 3, and 6 months after starting the study for a follow-up interview and to give a urine sample. You will be paid for each interview (\$25 in gift certificates or by another form of payment to be decided on by your treatment program). If you return for all of these interviews, you will be paid an extra \$25.
7. All of the information that you give us, including urine test results, will be kept confidential.

Questions about the study

These are the answers to some questions about the study that may help you decide if you would like to take part in the study.

1. How long will I be in the study?

You will get medications for about two weeks and then return for follow-up visits at 1, 3, and 6 months. Therefore, you will be in the medications phase for about two weeks and in the follow-up phase for up to 6 months.

2. How many people will be taking part in the study?

At least 360 people across the United States will take part in the study.

3. What will I have to do during the study?

There are a few things that you will have to do above and beyond your regular treatment if you decide to take part in the study, such as:

- * Take your study medication as your doctor prescribes
- * Go to your counseling sessions as usual
- * Fill out questionnaires and give urine samples at certain times
- * Return for study visits
- * Contact the clinic if you have any health problems between visits

4. Can women who are able to have children take part in the study?

Yes. However, because the safety of the study medications is not fully known, women who are able to have children should avoid becoming pregnant while in the medication phase of the study. If you are a woman able to have children, you will need to use birth control during the study and you will get a pregnancy test prior to participating. Acceptable methods of birth control will be discussed with you before you agree to participate in the study. Be sure to call your doctor right away if you think you are pregnant during the study.

