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 become 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 medication used in this study may help with your withdrawal symptoms while you stop using opiate drugs. You will get additional monitoring of your symptoms during the study, which might not be available to you otherwise. The study medication may help you stop taking other opioid drugs and may help you change to a drug free life. Finally, you will be compensated for your participation according to local policy at the site, for doing the screening/baseline, regular and follow-up visits (the most you can make if you complete all the visits is $185.00).

Questions About the Study

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

The medication used in this study has many possible side effects. During your participation in the study, you will be watched for known side effects of the medication. Still, some side effects may be harmful and some may be unknown. The study medication 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 the study doctor before taking any other medication along with the study medication.

You should know the possible side effects of a medication before you decide to take it. Buprenorphine itself may cause physical dependence. It can also cause intoxication and mild respiratory depression. If you stop taking it abruptly, you may experience opioid withdrawal symptoms. You may also be more sensitive to the effects of opioids when you detoxify from heroin, BUP/NX or other opioids. Your informed consent paper will list the side effects for the study medication.

Also, much of the information collected during the study is sensitive and there is a small risk that others who are not involved in the study will see it. However, 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 the clinic.

We have also obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). The Confidentiality Certificate will protect the investigators from being forced, even under a court order or subpoena, to release any research data in which you are identified. However, it does not apply to disclosure of medical information in cases of medical necessity.

For More Information

For more information on the National Drug Abuse Treatment Clinical Trials Network, visit the NIDA website at *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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CONTACT INFORMATION

CTN-0003

National Drug Abuse Treatment

Clinical Trials Network

Suboxone (Buprenorphine/ Naloxone) Taper:

A COMPARISON OF TAPER SCHEDULES

Should I Join?

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

Revised June 2003

NIDA NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

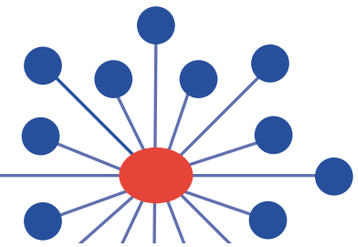
Researchers have shown that the combination of buprenorphine and naloxone (BUP/NX) is effective for treating opioid addiction. Buprenorphine is an analgesic that has just been approved by the Food and Drug Administration as an alternative to methadone treatment. Naloxone is an opioid antagonist used to prevent opiate overdose. The BUP/NX combination comes in a pill that you hold under your tongue until it dissolves

The National Drug Abuse Treatment Clinical Trials Network is doing a study called *Suboxone (Bup/Nx) Taper: A Comparison of Taper Schedules* to find out what medication schedule works best for patients when they are tapered off BUP/NX after they have been on it for at least a month. In this study, the Bup/NX medication will be provided free of charge.

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 out how to best taper people off this medication when they have been stabilized on it for at lease one month. If you want to get off opioids in a fairly short period of time (2 months or less), you might want to participate in this study.

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



document. You may ask as many questions as you want to help you decide whether or not to join. Also, a study doctor, nurse and/or research assistant will interview you to determine if you are eligible to participate in the study. This is called the screening/baseline 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. After it has been determined that you are eligible to participate, you will be inducted onto BUP/NX over a period of 3 days. Your doctor will discuss with you the medication that you will be receiving and give you instructions on how to take it. For the next 18 days, you and your doctor will determine which of three doses of BUP/NX works best for you. For the final week (7 days) before the taper begins, you will stay on one stable dose of BUP/NX each day.
2. After you are stabilized, you will be gradually tapered off the study medication. You will be randomly assigned (for example, by the toss of a coin) to taper off the medication in either 7 days or 28 days. Randomization means you will not have the choice of which schedule (either 7 days or 28 days) you will get.
3. Your doctor will follow you closely while you are on the medication. A blood test will be done when you are assigned to a taper schedule and one month later, in order to monitor your liver function.
4. Once you have finished the taper, you will be asked to continue weekly visits to the clinic for two months. This means if you are in the 7-day taper group you will come for 7 more weeks after you finish the taper and if you are in the 28-day taper group you will come for 4 more weeks after you finish the taper. At each of these visits, you will be asked to give us some important information about how you are feeling and how you are doing trying to stay off opioids. We can give you referrals for additional treatment to help you stay clean after you finish the taper.
5. After you complete your weekly clinic visits, we will also ask that you come back two more times, in about 1 to 2 months. At these visits, we will again ask you how you are feeling and how you are doing. We will ask you to tell us about any drug use and we will ask you to have your urine tested for drugs of abuse.
6. You will be compensated for your participation according to local policy at the site.
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?

Initially, you will visit the clinic once per week for 3 months. Then, you will be asked to return for two follow-up visits after 1 to 2 more months. Depending on which taper schedule you are assigned to, you will be taking medications for 35 or 56 days. Your total participation, including screening and follow-up visits, will be no longer than 5 months.

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

Approximately 480 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 the study medication as your doctor prescribes
- Do not use any benzodiazepine medications such as lorazepam or diazepam
- 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 medication for fetuses 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 and during participation. Acceptable methods of birth control will be discussed with you before you agree to participate in the study. Be sure to call the study doctor right away if you think you are pregnant during the study.