

## Introduction

Congratulations on making the choice to stop using drugs! You are invited to take part in a study of a test medicine called Suboxone. This clinic is studying whether Suboxone and Subutex, together with counseling, helps young adults stop using heroin and related drugs (called opioids). The clinic is part of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN), which aims to improve drug treatment across the nation.

## More about Suboxone and Subutex

Suboxone is a pill that contains two different medicines, buprenorphine and naloxone. Subutex only contains buprenorphine. Buprenorphine is a medicine that is used to prevent the withdrawal symptoms people experience when they stop using opioid drugs. These symptoms can include depressed mood, anxiety, drug craving, nausea, diarrhea, vomiting, muscle and joint aches, muscle spasm, runny nose and eyes, sweating and difficulty sleeping. Naloxone is a drug that reverses the effects of opioids. It can cause withdrawal symptoms. Giving naloxone and buprenorphine together in Suboxone may make it easier to use each medicine properly. The U.S. Food and Drug Administration has approved Suboxone for individuals 16 and older.

Everyone in the study will get all the usual services given at this clinic including counseling. Everyone will also get Suboxone treatment. Half of the people will take Suboxone for 7-14 days and half will take Suboxone for three months. This study will find out which way of using Suboxone is most helpful.

There are other types of drug treatment available at this clinic that do not include Suboxone and Subutex, so you do not have to be in the study to get treatment. If you choose not to take part in this study, you can still get all the other available treatment services at this clinic if eligible.

## What is involved?

If you want to be in this study, you will have to provide written permission. This is called informed consent. A staff member will discuss the study with you. They will also answer any questions you have that may help you to decide if you should take part in this study.

You will have to give written permission for two separate parts of the study. The first part is called a screening, and it checks to see if you meet the requirements and are able to take the study medication. The screening involves:

- Blood and urine tests to check for drugs and general health
- A pregnancy test for females
- A physical exam by a doctor or nurse practitioner
- Electrocardiogram and alcohol breath test
- Questions about your health, mood and behavior
- Questions about your drug use and treatments

If the screening tests show that you can take the medicine, we will offer you the study and request written permission for the treatment part of the study. Before you can provide permission to take part, you will have to pass a quiz to show that you understand the study.

If you decide to join the study, here is what you can expect:

1. Because this is a study, the researchers will assign you to one of the Suboxone treatment groups. Patients will be assigned to groups by chance (like flipping a coin). You will not get to choose which Suboxone treatment you will receive. Everyone in the study will get drug counseling and will attend weekly research visits to check the effect of treatment for three months. Everyone will continue with study visits after the 3 months.

**Group 1.** Patients take Suboxone for 7-14 days. The dose of Suboxone will gradually get smaller over the 7-14 days.

**Group 2.** Patients take Suboxone for three months. The dose of Suboxone will gradually get smaller during the third month.

2. The doctor or nurse will teach you how to take the medication. In most cases, you will have to come to the clinic to get each tablet of medication. For the first few days, you will have to stay in the clinic for up to three hours. During this time, the doctors will check to see how you react to the medicine so they can find the right dose. On the rest of the days, you will be able to leave the clinic after taking their medication, unless there are additional study tasks to do for that day. You should not drive or operate heavy machinery until you have adjusted to the effects of the medication.
3. Your doctor will watch you closely while you are taking the medicine to make sure you are taking it properly and to see how you are doing. Your doctor may give you other medications for treatment of withdrawal symptoms (for example, nausea, diarrhea, or trouble sleeping).
4. For the first three months of the study, you will need to come to the clinic once per week for research visits lasting 10-15 minutes. These can be scheduled at the same time that you come for your medication. Please keep the site staff informed about any changes in your contact information such as telephone number. During those visits, the following things will happen:

- Urine test to check for drugs
- Pregnancy test if female and taking medication
- Breath test to check for alcohol
- Questions about medication use
- Questions about how you are doing

5. For the first three months, you will also need to take part in one individual and one group counseling session each week. After that, your counselor will decide how often you should come for counseling. We hope you will also attend family counseling as well as self-help groups geared toward young adults.

6. You will also need to come to the clinic for longer research visits at six other times during the study. These visits will take place 1, 2, 3, 6, 9, and 12 months after starting Suboxone. The visits may last up to 2.5 hours. During those visits, some or all of the following things will happen:

- Blood tests for general health check
- Urine test to check for drugs
- Breath test to check for alcohol
- Physical exam for general health check
- Questions about medication use
- Questions about how you are doing

7. Even if you decide to stop taking Suboxone or to stop coming to the counseling sessions, we would like you to come to each of the research visits so we can continue to check how you are doing. Please keep the study staff informed of any changes to your contact information. You will be paid for the time and effort it takes to attend these research visits. **PAYMENTS WILL NOT BE MADE IN CASH.** Instead, the clinic may provide vouchers, certificates for merchandise, or some other type of payment.

## Questions about the study

These are the answers to some questions about the study that may help you decide if you should take part

### 1. How long will I be in the study?

The study will last for one year. You will come to the clinic weekly for three months, and at 6, 9, and 12 months after taking your first dose of medication.

### 2. How many people will take part in the study?

About 240 people across the country will be in the study.

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

There are a few things you will have to do if you join the study, including:

- Take the medication as directed. In most cases this will require daily visits to the clinic.
- Attend all research visits and fill out some questionnaires
- Give urine and blood samples
- Call the clinic if you have any side effects or health problems

### 4. Can women who are able to get pregnant take part in the study?

Yes, but only if they take steps to avoid getting pregnant. We don't know if Suboxone can harm an unborn child. If you are sexually active, you will have to use birth control while taking Suboxone. You will have pregnancy tests several times during the study to make sure that you are not pregnant while taking the medication. If you think you may be pregnant, make sure to tell the study doctor right away.

### 5. What will I get for taking part in this study?

The Suboxone and Subutex will be provided for free, and it may help you to stop using drugs. Being in the study will give you more contact with clinic staff. This extra attention from doctors, nurses and counselors may help you.

## Questions about the study

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

Any medication can have unwanted or bad effects. The possible bad effects of Suboxone and Subutex will be discussed with you before you start the study. There will also be a list of bad effects on the paper you will read and sign before starting the study. Some of the possible bad effects of Suboxone and Subutex include irritation in the mouth, headache, changes in sleep (too tired or can't sleep), nausea, constipation or dizziness. Other kinds of bad effects, like liver damage, could also occur.

Serious bad effects, including overdose or death, can occur if you continue to use heroin, other drugs (especially drugs like Valium or Xanax), or alcohol while you are on the study medication. 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, Buprenorphine/Naloxone or other opioids. When you first start taking the pills, you may become tired, uncoordinated and/or have clouded thinking. As a safety precaution, you should not drive or operate machinery until you get used to these effects or the effects go away. Bad effects can also occur if you use the drug in a way other than what was intended.

The study doctor will monitor you for side effects each time you come to a study visit. You should call the study doctor if you have any problems with the medications.

Bad effects can also happen if you continue to use opioids and do not receive treatment.

## Questions about the study

### 7. Will anyone see my private information?

Much of the information collected during this study is personal and private. There is a very small risk that people not involved in the study might see your information. The study staff is trained to keep your information private. Your name will not be on any information that leaves this clinic, and private information will not be shared, except in certain cases. Some institutions that are involved with the study are allowed to look at your information, including the National Institute on Drug Abuse, the Department of Health and Human Services, and research review committees working with your clinic and study staff. Individuals at these institutions will not reveal your name or private information. Certain types of information must be reported to authorities and will not be kept private. If the study staff believes you are a risk to yourself (have thoughts of harming or killing yourself) or to others (have thoughts of harming or killing others), they must act on that information. In some states, study staff must report cases of communicable diseases, such as HIV/AIDS or hepatitis.

## For More Information

National Institute on Drug Abuse  
Center for the Clinical Trials Network  
6001 Executive Boulevard  
Room 4234, MSC 9557  
Bethesda, Maryland 20892-9557  
Telephone: (301) 443-6697  
Fax: (301) 443-2317

Further information on the Clinical Trials Network can be accessed through the NIDA website at

[www.drugabuse.gov](http://www.drugabuse.gov)

CTN-0010

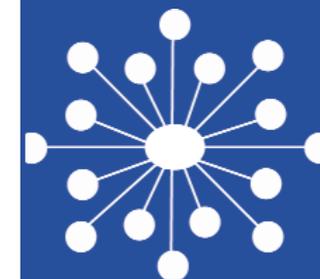
**NIDA** NATIONAL INSTITUTE  
ON DRUG ABUSE

*National Drug Abuse Treatment*

# Clinical Trials Network

Young Adults  
18-21:  
Read about a  
Narcotics  
Treatment Study  
Designed  
Just for You

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



National Institutes of Health  
U.S. Department of Health and Human Services