

## Introduction

Congratulations on your choice to stop using drugs. You are invited to join a study that is testing whether a medicine called Suboxone, along with drug counseling, helps teenagers stop using heroin and related drugs (called opioids). The clinic is part of NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN works to improve drug treatment across the nation.

## More about Suboxone and Subutex

Doctors still do not know the best way to help addicted teenagers stop using heroin and related drugs (opioids). A new medication has been shown to help adults addicted to opioids, but it is not known if it will help teenagers in the same way. This clinic, along with the The National Drug Abuse Treatment Clinical Trials Network (CTN), is doing a study (an experiment) to find out if this medication will help teenagers who are addicted to opioids.

Suboxone is a pill that has two different medicines inside, buprenorphine and naloxone. Buprenorphine is a medicine that is used to reduce unpleasant withdrawal effects people have when they stop using opioid drugs such as heroin. Naloxone is a medicine that reverses the effects of heroin and related drugs. Giving these medicines together in one pill makes it easier to use them properly. Subutex only contains buprenorphine. The U.S. Food and Drug Administration has approved Suboxone.

Everyone in the study will get all the usual treatment at this clinic. Everyone will also get Suboxone treatment. Half of the people will take Suboxone for 7-14 days and half will take it for three months. This study will find out which way of using Suboxone is best. If you are in the study, you will not get to choose which way to take Suboxone. Your treatment will be assigned to you by chance, like the flip of a coin.

This clinic gives other kinds of drug abuse treatment besides Suboxone and Subutex, so you do not have to be in the study to get help. If you choose not to take part in this study, you still have other treatment choices at this clinic if eligible.

## What is involved?

There are other types of treatment for heroin abuse available at this clinic, so you do not have to be in the study to get help. If you choose not to be in this study, the staff will still provide you with all the services they can to help you stop using drugs.

If you want to be in the study, you will have to talk it over with your parent or guardian. We will need their written permission to allow you to take part. A clinic counselor or study coordinator will discuss the study in detail with you and your parent(s) or guardian. You will have a chance to ask questions that may help you and your parent(s) or guardians decide if you should join.

Because you are under 18, they will have to give written permission for you take to part (informed consent). You will also have to give written permission (assent). A staff person will tell you and your parent/legal guardian more about the study so you can decide if you should take part. You and your parent/guardian will be asked to give permission for two separate parts of the study.

Before you start the treatment, you will be checked to see if you are able to take the medicine in this study. You and your parent/legal guardian will have to give written permission for these tests:

The first part is called a screening, and it checks to see if you meet the requirements and are able to be in the treatment part of the study. Since this is research, there are certain requirements that have to be met in order for you to take part. The screening involves:

- Blood and urine tests to check for drugs and general health
- A pregnancy test if you are female
- A physical exam by a doctor or nurse

- Electrocardiogram and alcohol breath test
- Questions about your health, mood and behavior
- Questions about your drug use and treatments

If you meet all the requirements of the screening, you will be offered the study and you and your parent/guardian will be asked to give written permission for the treatment part of the study. This is called informed consent. Before you can sign up for that part of the study, you and your parents/guardians will have to pass a quiz showing that you understand what is involved.

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

1. Everyone in the study will get drug counseling. Everyone will come to weekly research visits for 3 months, to see if the treatment is helping. Everyone will continue with study visits after the 3 months. You will be in one of two medicine groups:

**GROUP 1.** People in this group will take Suboxone for 7-14 days.

**GROUP 2.** People in this group will take Suboxone for three months.

2. The doctor will teach you how to take the medicine. You will probably have to come to the clinic to get each tablet of medicine. For the first few days, you will have to stay in the clinic for up to three hours. 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 the medicine, unless there are more study tasks to do for that day. You should not drive or operate heavy machinery until you have gotten used to the effects of the medicine.
3. Your doctor will watch you closely while you are taking the medicine to make sure you are taking it correctly and to see how you are doing. Your doctor may give you other medications if you need it for withdrawal effects from stopping drugs.

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 medicines. 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 medicine
  - Breath test to check for alcohol
  - Questions about medicine 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 need to come. We hope you will also go to family counseling and group counseling for people your age.
  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 and Subutex. 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
    - Electrocardiogram
    - Physical exam for general health check
    - Questions about medicine use
    - Questions about how you are doing
  7. Even if you decide to stop taking Suboxone or Subutex, 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. You will be paid for the time and effort it takes to attend these research visits. **PAYMENTS WILL NOT BE MADE IN CASH.** Payments will be made in vouchers, certificates for things that you can buy, or in some other form.

## Questions about the Study

These are the answers to some questions about the study that may help you and your parent(s) or legal guardians 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 every week for three months, and at 6, 9, and 12 months after taking your first dose of medicine.

### 2. 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 medicine as directed. In most cases you will have to come to the clinic every day to get your medicine.
- Come to all research visits and fill out some questionnaires
- Give urine and blood samples
- Call the clinic if you have any bad effects or health problems

### 3. Can girls who are able to get pregnant take part in the study?

We don't know if Suboxone is bad for an unborn child. If you are having sex, 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 medicine. If you think you may be pregnant, make sure to tell the study doctor right away.

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

You will get the study medicine for free, and it may help you to stop using drugs. You will also get more chances to meet with clinic staff. The extra attention from doctors, nurses and counselors may help you.

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

Any medicine 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 medicine. 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. For safety reasons, 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 medicine in a way different than you were told.

The study doctor will check 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 medicines.

Bad effects can also happen if you keep using opioids and do not get treatment.

### 6. 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 are 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. People at these institutions will not give out 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. They must also report any suspected instances of child abuse or neglect. In some states, study staff must report cases of communicable diseases, such as HIV/AIDS or hepatitis.

There is a chance that information about your health or behavior (for example, pregnancy) may be shared with your parent or legal guardian. This will be decided at each clinic according to the laws of your state. The study coordinator at your clinic can tell you the rules for your state.

### 7. What if my parent/legal guardians won't let me join?

Since you are under 18, you cannot be in the study without permission from your parent or legal guardian. If you do not get permission to be in the study, you can receive other treatments from the clinic if eligible.

## For More Information

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

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

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## National Drug Abuse Treatment Clinical Trials Network

Teenagers 14-17:  
Read about  
a Narcotics  
Treatment  
Study Designed  
Just for You

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



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U.S. Department of Health and Human Services