

STUDY OVERVIEW

Dr. YYYY's Pain Medication Study

THIS IS NOT YOUR CONSENT FORM – IT IS AN INTRODUCTION TO THE STUDY

You are being asked to participate in a study because you have severe chronic pain that is not due to cancer.

Participation means extra visits to the clinic and tests that may cause you some physical pain.

WHAT'S THE STUDY ABOUT?

This study is about a new pain medicine that is a non steroidal anti-inflammatory drug (NSAID) rather than an opiate pain killer.

WHAT ARE YOU ASKED TO DO?

First, we have to see if you qualify for the study.

You will have to do these things first if you join the study:

- Have a complete physical exam and we need a list of all medications you take
- Scans (like x-rays) of your joints that are affected by pain
- Pregnancy test if you are a woman
- A physical therapy assessment to detect your ability to move freely (range of motion)
- An ECG to check on how healthy your heart is (a simple recording that is painless and will not harm you)
- Endoscopy (a tube that lets doctors see inside your body) of your esophagus and stomach to see how healthy your stomach lining is

WHAT NEXT?

If you join the study, you will go into one of two groups. One group will get ibuprofen and the other group will get the new medication. You will get into a group randomly – that is, just as if we flipped a coin to decide.

You will be given a two week supply of this your medication.

You will be asked to come in to our clinic to be assessed for your pain levels and range of motion. Around week 10 you will again be asked to have a scope put in your esophagus and into your stomach. This is to make sure you are not having bad side effects.

Your doctor will not know which medicine you are getting. However, if you get sick, your doctor can find out which medicine you took from the drug company's 24-hour information line.

RISKS

There are some risks to using this new medicine just like there are for ibuprofen. You might get ulcers or begin to have bleeding in your stomach. The new drug might also cause increased acid in your stomach and give you heartburn.

There is a possibility you might have a slight increased risk of heart problems.

Also, this drug may interfere with some of your other medications so you need to make sure your study doctor knows what you are taking.

BENEFITS

Joining the study may not help you, but your condition could get better with this treatment.

COST

It won't cost you anything but your time in participating in this study

REWARDS

We will pay you for participating in some of these tests and visits - \$100 for each visit to evaluate your pain and range of motion. We will pay you another \$200 for the endoscopy sessions

IF YOU DO GET SICK BECAUSE OF THIS STUDY

If the medications in this study cause you to get sick or have bad side effects, tell Dr. YYYY immediately. If your condition is because of the new drug, the drug company will pay for your care. Your other health problems will be paid for by your insurance as usual.

CONFIDENTIALITY

We will protect your privacy and confidentiality of records as the law permits. The company that makes this new medication wants to see the data and their staff may look at your medical records to make sure everything is done right.

NOW, we are going to go over your consent in detail. You may keep this as a quick reference to the main parts of the study.