

Study Title for Participants: Duloxetine to prevent oxaliplatin-induced peripheral neuropathy

Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: Protocol A221805, “Duloxetine To Prevent Oxaliplatin-Induced Chemotherapy-Induced Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Phase II To Phase III Study,” (NCT # 04137107)

You are currently participating in the above research study. The study has been changed to help the researchers learn more from this study. Because you are a participant in this research study, it is very important that you read this.

What has happened?

The researchers developed educational materials for participants using electronic patient reported outcomes (ePRO) surveys after this study was started. The purpose of this sub-study is to test the impact of the educational materials. Patients are divided into two sub-groups: one for those who enrolled in the main study before the educational material was available, and another for those who enrolled when the educational material became available. Results from the two groups will be compared.

You began the main study before the educational materials were available. Your information is important whether you completed your surveys with paper booklets or using ePRO and the Patient Cloud app.

Taking part in this sub-study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. You may continue participating in the main duloxetine trial if you choose to not take part in the sub-study.

What is the purpose of this sub-study?

The purpose of this sub-study is to test a new training video and written instructions that may help patients to make an informed decision about whether to complete surveys using paper or electronically. The training video together with the written materials are known as the “ePRO-E toolkit”. The information from patients using ePRO-E toolkit will be compared to that of patients who did not have access to the toolkit.

What is the usual approach to deciding between electronic or paper booklets?

The usual approach is to offer patients the choice without having access to the ePRO-E toolkit.

What is involved?

If you agree to provide additional information, we will ask you to complete a survey using paper. The survey is about your experiences and attitudes related to the use of technology. The survey will take about 10 minutes to complete. You will also be asked to share personal information that includes your income and educational levels at the time you started the study. This information will be kept in a central research database along with other information such as your response to cancer treatment or results of study tests. However, your name and contact information will not be put in the database. Your privacy is very important to us.

In addition, you may be selected to take part in a telephone or video interview. The interview will last about 60 minutes and will take place when it is convenient for you. The interview will focus on your experiences and attitudes about technology. You will be asked to provide your email address now so that the research team may contact you if you are selected to participate in the interview. If you choose to participate in the interview by telephone, it will be necessary for you to provide your telephone number. Your contact information will be kept only for the duration of the study. If you agree to take part in the interview, you will receive a \$50 gift card by email as a thank-you gift.

You don't have to answer any question that makes you feel uncomfortable. If you do not want to complete the additional survey, share your income and education, and/or complete the interview if chosen, you may still continue to participate in the main duloxetine study and will continue to be followed.

I have been given a copy of the 2 pages of this consent addendum. I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in this sub-study.

Participant Signature: _____

Date: _____

Signature of Person Obtaining Consent: _____

Date: _____