NCI Community Oncology Research Program – Kansas City (NCORP-KC)

NRG-CC004 Consent Form

Study Title for Study Participants: Comparing Two Dose Levels of Bupropion Versus Placebo for Sexual Desire

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: NRG-CC004 Phase II Double Blind Dose Finding Trial of Bupropion Versus Placebo for Sexual Desire in Women with Breast or Gynecologic Cancer

What is the usual approach for sexual health in women who have been treated for gynecologic and breast cancers?

Long term consequences of the cancer experience can include unwanted changes in sexual health. People who do not take part in this study may receive counseling or use topical lubricants to improve aspects of their sexual health.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available

Why is this study being done?

Sexual health after treatment for cancer is an important survivorship issue. This study will address the common side effect of decreased sexual health in women who have been treated for breast or gynecologic cancer. The study will test whether bupropion, a medication that is approved for depression and smoking cessation can improve sexual desire compared to placebo.

A placebo is a pill that looks like the bupropion but contains no medication.

There will be about 234 people taking part in this study.

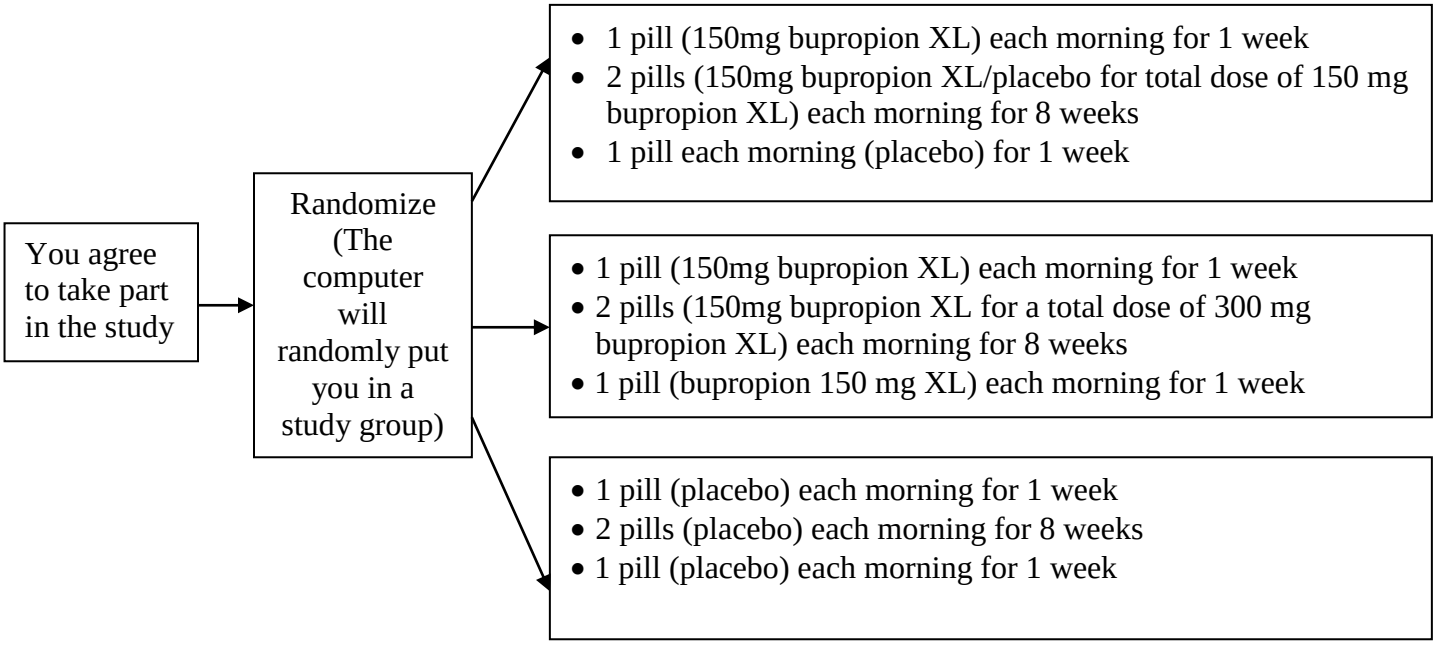
What are the study groups?

This study has three study groups. Two different doses of bupropion, 150 mg extended release (XL) and 300 mg extended release (XL), will be compared to a placebo. Participants will be randomized into one of three study groups described below. A computer will by chance assign you to treatment groups in the study. This is done by chance because no one knows if one study group is better or worse than the others. You will have an equal chance of being placed in any of the three groups. Neither the research team nor you will know which group you are assigned to.

Each group will be supplied with 4 bottles of pills which will come in a kit with an instruction sheet.

You will take 1 pill each morning for 1 week, then take 2 pills each morning for 8 weeks, and then take 1 pill each morning for 1 week.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in this study?

You will receive bupropion, or placebo or a combination of bupropion and placebo for a total of 10 weeks.

Do not crush, chew or cut the capsules as that will change the way the medicine is delivered and can be harmful. You may take the capsules with our without food. Take them with a full glass of water. Do not stop this medicine suddenly before talking with your provider. If you start any new medicine including over the counter medicine, please let your provider know as some medicine can interact with this medicine.

If you are assigned to the group that gets only placebo, you will be given the option to try the study drug, provided by the study. If you choose to participate you will take bupropion for a total of 8 additional weeks after you have completed the first 10 weeks of study treatment and returned all of the study materials.

What extra tests and procedures will I have if I take part in this study? (9/8/17)

There are no extra medical tests or medical procedures that are required to take part in this study. You will be asked to complete questionnaires that ask about your sexual desire, your sexual health, fatigue, mood and your quality of life. You will be asked to complete these questionnaires 3 times during the study; before you start taking bupropion and during treatment at 5 weeks and 9 weeks. Two questionnaires will only be completed at the beginning of the study, one that asks about your relationship with your partner and one that asks about your self image. You will also be asked to fill out a questionnaire about any side effects or negative effects you feel you are experiencing from the medication. This information will be filled out at the end of weeks 1, 2, 5, 7 and 9 during treatment. All study related questionnaires can be completed during an office visit, by phone or filling it out at home using paper and pen.

If you are in the placebo group and choose to try bupropion for 8 extra weeks you will be asked to complete questionnaires at weeks 4 and 8 after starting the buproprion.

At the end of the study, all participants will be asked about the overall level of satisfaction and how much you feel you benefited from the study medication.

In the past, patients often have filled out these quality of life forms on paper. NRG Oncology is working with a company, VisionTree Software, Inc., that has a web site where patients can fill out these forms anywhere there is a computer with Internet access. This option is being offered as some patients may find it more convenient to fill out the forms electronically from any location, including home. When you log on to the web site, it will take you through the process of completing the forms step by step. You will need an e-mail address that you agree to use for this purpose. The e-mail address is needed to identify you on the VisionTree web site and for e-mail reminders that will be sent to you when the forms are due. Your e-mail address will only be used for the purpose of this study, not for mail or marketing purposes. If you are interested in filling out quality of life forms electronically but do not have an e-mail address, you may obtain one (quickly and for no charge at web sites such as Yahoo!, Hotmail, or AOL). You will only be sent e-mail reminders at the time that the forms are due (a maximum of 3 e-mail reminders per time point). Your access to the VisionTree web site is password protected and secure. You can use your e-mail address to retrieve your password if you forget it or lose your login card. You will receive a login card either by regular mail or e-mail, and it will include the information you need to log in to the VisionTree web site the first time. All patients will complete the forms before treatment on paper. After that, you can choose to complete the remaining forms online or on paper. The choice is up to you.

Please circle your answer: I choose to use the VisionTree Software. I agree to fill out the Quality of Life forms electronically (after treatment has started) using the VisionTree web site.

YES NO

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- Bupropion may not be better, and could possibly be worse, than the usual approach of counseling for sexual health.

There is also a risk that you could have side effects from bupropion.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust bupropion to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible side effects of bupropion

COMMON, SOME MAY BE SERIOUS In 100 people receiving bupropion, more than 20 and up to 100 may have:
• Headache • Nausea • Dry mouth • Difficulty sleeping • Loss of appetite • Weight loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving bupropion, from 4 to 20 may have:
• Constipation • Dizziness • Abnormal body movement • Restlessness, Worry • Infection • Stomach, muscle, bone pain • Abnormal heartbeat • Diarrhea • Mood changes, irritability • Sweating, rash,itching • Runny nose, sore throat • Ringing/buzzing in the ear

RARE, AND SERIOUS In 100 people receiving bupropion, 3 or fewer may have:
• Severe allergic reactions • mood problems • psychiatric problems (such as hallucination, psychosis, agitation, confusion) • Seizure • High blood pressure

In patients taking bupropion for depression and other mental health disorders, increased depression and/or suicidal thoughts and behaviors is a rare and serious side effect. In addition, patients taking bupropion for smoking cessation have experienced serious changes in mood and behavior. Although patients in this study are not being treated for depression and the formulation of bupropion is different than that approved for smoking cessation, it is important to be aware of these additional rare and serious side effects. Tell your doctor if you experience any side effects, including changes in mood and behavior.

One of the questionnaires asks about depression and anxiety. If you score 9 or more on this questionnaire, study personnel will be required to let your provider know and a health care provider will talk to you further to determine whether you need emotional support or treatment more urgently.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if bupropion is better than the usual approach so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. You should not stop the study medication without talking to your study team. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this study?

Bupropion will be supplied at no charge while you take part in this study. You and/or your health plan/insurance company will need to pay for all of the costs of your usual health care while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance

company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.
There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- NRG Oncology
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- VisionTree Software, Inc.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Main Study

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 copy of this form. I agree to take part in the study.

Participant Name_____

Participant Signature _____ Date _____

Person Obtaining Consent_____

Signature of Person Obtaining Consent_____

Date _____