The exams and medical tests required before you begin the study:

- Medical history and physical exam
- Blood test (to look at kidney function and to rule out pregnancy – if you arepre-menopausal).

How will I participate?

- You will be randomly chosen (by chance) to begin with Venlafaxine (Effexor®) or Gabapentin (Neurontin®).
- You will receive the first treatment for four weeks. Once you have completed four weeks of the first treatment, you will come off the medication for two to four weeks (wash-out time) after which you will begin the second treatment for the next four weeks.
- That way you will have a chance to **evaluate** both treatments and to give your **preference**.
- During the study, you will be asked to complete diaries and questionnaires.
- You will be seen in the clinic three times: at the beginning of the study, at the beginning of second treatment period and at the end of the study.

How long I will be in the study?

You will be in the study for a total of 12 to 14 weeks. This study is run by doctors who lead a team of medical and research professionals.

Before you take part in the study, you will have the opportunity to discuss all aspects of the study with your Medical Oncologist and research staff.

If you have any questions about your rights as a research study participant, please call Dr. R. Heslegrave, Chair of the Mount Sinai Hospital Research Ethics Board at 416-586-4800 ext. 4875. This person is not involved with the research project in any way and calling him will not affect your participation in the study.

If you would like to learn more about this research study, please contact your Medical Oncologist or call Olivera Jugovic at 416-586-4800 ext. 5553.

The Principal Investigator of this study is Dr. Louise Bordeleau, Medical Oncologist at 416-586-4800 ext. 3202.

Funded by
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Vibrant Study

Hot Flashes Research Study in Breast Cancer Survivors

What is the Vibrant study?

It is a type of scientific research study.

The purpose of the Vibrant study is to **compare two non-hormonal drugs: Effexor® (venlafaxine)** and **Neurontin® (gabapentin)**, to see which one is more effective in decreasing or stopping hot flashes in women and to determine which drug has fewer side effects. You can help us to determine which of theseoptions (Effexor® vs. Neurontin®) is better in controlling hot flashes by evaluating bothmedications and giving your preference.

Why should I participate?

Both study drugs have been shown to be effective in reducing hot flashes. The study will provide information for future patients about how effective the study drugs are as well as the side effects. You will contribute to clinical research and help make progress in science and patient care.

Why is this study being done?

Hot flashes and other menopausal symptoms (memory loss, difficulty concentrating, insomnia, mood swings and vaginal dryness) are common and tend to be more severe and last longer in breast cancer survivors compared to womenwho have not had breast cancer.

Hot Flash Definition:

> The sudden, intense, hot feeling on your face and upper body accompanied by sweating, rapid heartbeat, anxiety, irritability, dizziness and weakness.
>
> Hot flashes may last a few seconds or as long as 30 minutes. Most last no longer than two or three minutes.

What causes hot flashes?

Hot flashes are mostly caused by the hormonal changes of menopause. A diminished level of Estrogen has a direct effect on the hypothalamus, the part of the brain responsible for controlling body temperature, appetite, sleep cycles and hormones. The decrease in Estrogen confuses the hypothalamus – which is referred to as the body's "thermostat"–and makes it read "too hot."

Who can participate in this study?

- Women with a history of breast cancer, DCIS (Ductal Carcinoma in Situ) and LCIS (Lobular Carcinoma in Situ)
- Currently without evidence of malignant disease
- Who completed chemotherapy or radiation therapy of more than eight weeks
- Bothersome hot flashes (at least 14 times per week)
- Presence of hot flashes for more than a month before entering study
- Normal kidney function
- Aged 18 or older

Who cannot participate in this study?

- Previous use of Venlafaxine (Effexor®) or any other antidepressants within a year
- Use of Gabapentin (Neurontin®) within two weeks of study entry
- Current (less than two weeks) or planned use of other medication for hot flashes
- Certain drugs for treatment of high blood pressure (Calcium Channel Antagonists)
- Pregnant or breastfeeding