PURPOSE OF STUDY

Sleep disturbances, particularly insomnia, are far more prevalent in cancer patients than in the general population.

Our study will examine the effectiveness of current treatments, such as Brief Behavioral Therapy for Insomnia and Armodafinil (Nuvigil®), in preventing and reducing insomnia and fatigue in breast cancer patients.
Researchers at Stanford Cancer Center are conducting a study funded by the National Cancer Institute to determine the most effective way to treat and prevent insomnia and fatigue in breast cancer patients. We are looking for women with breast cancer who have 6 weeks of chemotherapy remaining. They must be at least 21 years old and experience sleep difficulties. The participation in this study is completely voluntary.

The goal of this study is to examine the effectiveness of Armodafinil (Nuvigil®) and Brief Behavioral Therapy for Insomnia separately and together in the treatment and prevention of insomnia and fatigue in breast cancer patients. There is currently no standard treatment for insomnia and fatigue in cancer patients. This research can shed new light on effective treatments for women with breast cancer having sleep difficulties.

The study will include:

- Wearing a watch-like device (Actiwatch) that measures sleep activity throughout the study.
- Collecting saliva samples at home.
- Blood draws to measure inflammation at 4 time points.
- Completing questionnaires and daily diaries.
- Taking medication, either placebo or Armodafinil (Nuvigil®) - medication designed to treat sleepiness for 6 weeks.
- Phone calls and face to face Brief Behavioral Therapy for Insomnia sessions several times throughout chemotherapy treatment.

Each participant will be randomized to one of the following arms:

- Placebo daily for 6 weeks.
- Armodafinil (Nuvigil®) daily for 6 weeks.
- Brief Behavioral Therapy for Insomnia and placebo daily for 6 weeks.
- Brief Behavioral Therapy and Armodafinil (Nuvigil®) for 6 weeks.

Benefits of Participation

All tests and medications will be provided free of charge. In addition, you will receive a meal after each blood draw.

The most important benefit is helping us better understand the most effective way to treat insomnia and fatigue in breast cancer patients.