

[NCI Home](#)[Cancer Topics](#)[Clinical Trials](#)[Cancer Statistics](#)[Research & Funding](#)[News](#)[About NCI](#)

## Clinical Trials (PDQ®)

[Patient Version](#)**[Health Professional Version](#)**

### Page Options

- [Print This Page](#)  
 [E-Mail This Document](#)

### Clinical Trial Questions?

Get Help:  
1-800-4-CANCER or  
[LiveHelp online chat](#)

### Quick Links

- [Help Using the NCI Clinical Trials Search Form](#)  
[Educational Materials About Clinical Trials](#)  
[About NCI's Cancer Clinical Trials Registry](#)  
[Dictionary of Cancer Terms](#)  
[NCI Drug Dictionary](#)

## Evaluation of Synthetic Thyrotropin Releasing Hormone (TRH) as a Treatment for Cancer-Related Fatigue

### [Basic Trial Information](#)

#### [Trial Description](#)

##### [Summary](#)

##### [Eligibility Criteria](#)

#### [Trial Contact Information](#)

### Basic Trial Information

Phase	Type	Status	Age	Sponsor	Protocol IDs
Phase II	Supportive care	Active	18 and over	Other	05-269-2 601, NCT00790296

### Trial Description

#### Summary

The primary objective of the study is to evaluate thyrotropin releasing hormone (TRH) as a treatment for cancer-related fatigue.

The central hypothesis of this pilot study is that TRH is more efficacious than placebo in alleviating cancer-related fatigue in patients with breast or prostate cancer.

#### Eligibility Criteria

##### Inclusion Criteria:

- Patients with a diagnosis of cancer who have undergone or are currently undergoing radiation or chemotherapy therapy and are expected not to have any significant change in cancer treatment sessions during the study period
- Provide written informed consent prior to initiation of any study-related procedures.
- Male or female, 18 years of age or older with a diagnosis of breast cancer or prostate cancer.
- Able to understand and comply with the requirements of the study.

##### Exclusion criteria:

- Hospitalized patients.
- Patients with an identifiable diagnosis of substance abuse or dependence within 6 months prior to evaluation (except those in full remission, or those with caffeine or nicotine dependence) as defined by DSM-IV criteria.

- Patients with any of the following cardiovascular symptomatology.
- Office systolic BP > 160mmHg and/or diastolic BP > 90mmHg.
- Persons with a resting hear rate of > 100 beats per minute
- Persons with a history of chronic stable angina
- Persons with myocardial infarction or unstable angina or vascular surgery within 6 months
- Persons with history of vaso-vagal or other syncopal episodes
- Patients with any known clinically significant cardiac problems
- Patients with any history of stroke or at significant risk for stroke.
- Patients with a history of seizures
- Patients with a history of asthma
- Patients with any clinically significant unstable or inadequately treated co- morbid medical condition or patients currently on medications that would confound evaluation of CF (e.g. diabetes, CHF, history of other cancers) as judged by the investigator.
- Patients with any clinically significant, unstable psychiatric disorder (except mild to moderate depressive or anxiety disorders) or patients on psychotropic medications that would confound CF assessment as judged by the investigator. Patients with history of depressive or anxiety disorders will not be excluded from the study
- Patients with a history of illnesses or treatments that would be expected to significantly alter immune function (viz. HIV infection, systemic lupus erythematosus, patients taking immunosuppressive medications).
- Patients with diseases or on medications that significantly affect the hypothalamic-pituitary-adrenocortical (HPA) axis function (viz. Cushings disease).
- Pregnant patients, breastfeeding or plans to become pregnant during the study
- Patients with known allergy to TRH
- Any other condition, which, in the opinion of the investigator, would make the patient, unsuited for enrollment, confound CF evaluation or could interfere with the patient's participation in the study.
- Patients with medically reversible causes of CF (viz., anemia, hypothyroidism, electrolyte abnormalities etc).
- Patients with potentially treatable associated symptoms dominating the CF scenario such as pain, or sleep disturbances which may have a significant causal relationship to CF.
- Patients identified as pregnant based on the pregnancy test during screening.
- Patients physically unable to complete the walking test (WT) assessment or when the WT would increase risk for medical complications

## Trial Contact Information

## Trial Lead Organizations/Sponsors

Carole and Ray Neag Comprehensive Cancer Center at the University of Connecticut Health Center

Susan G. Komen Breast Cancer Foundation

Carole and Ray Neag Comprehensive Cancer Center at the University of Connecticut Health Center

Andrew Winokur, MD PhD

Principal Investigator

Jayesh Kamath, MD PhD

Ph: 860-679-6727

Email: [jkamath@uchc.edu](mailto:jkamath@uchc.edu)

Andrew Winokur, MD PhD

Ph: 860-679-6775

Email: [winokur@psychiatry.uchc.edu](mailto:winokur@psychiatry.uchc.edu)

## Trial Sites

U.S.A.

## Connecticut

Farmington

### ***Carole and Ray Neag Comprehensive Cancer Center at the University of Connecticut Health Center***

Jayesh Kamath, MD PhD

Ph: 860-679-6727

Email: [jkamath@uchc.edu](mailto:jkamath@uchc.edu)

Andrew Winokur, MD PhD

Ph: 860-679-6775

Email: [winokur@psychiatry.uchc.edu](mailto:winokur@psychiatry.uchc.edu)

Andrew Winokur, MD PhD

Principal Investigator

---

[See All Trial Sites](#)

---

[Link to the current ClinicalTrials.gov record.](#)

NLM Identifier NCT00790296

Information obtained from ClinicalTrials.gov on October 25, 2009

---

Note: Information about this trial is from the *ClinicalTrials.gov* database. The versions designated for health professionals and patients contain the same text. Minor changes may be made to the *ClinicalTrials.gov* record to standardize the names of study sponsors, sites, and contacts. Cancer.gov only lists sites that are recruiting patients for active trials, whereas *ClinicalTrials.gov* lists all sites for all trials. Questions and comments regarding the presented information should be directed to *ClinicalTrials.gov*.

---

[▲ Back to Top](#)

---

[NCI Home](#) | [Text-Only Version](#) | [Contact Us](#) | [Policies](#) | [Accessibility](#) | [RSS](#) | [Viewing Files](#) | [FOIA](#) | [Site Help](#) | [Site Map](#)

A Service of the National Cancer Institute

